IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff.** **v.** **Arthrex, Inc.** **a Delaware Corporation, and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

Plaintiff DePuy Mitek's Memorandum In Support Of Motion *In Limine* (No. 4) To Limit The Testimony Of Arthrex's Patent Law Expert, Mr. Witherspoon

Plaintiff, DePuy Mitek ("Mitek") moves the Court to exclude two portions of the proposed testimony of John Witherspoon, the proposed patent law expert of Defendants Arthrex, Inc. and Pearsalls, Ltd. (collectively, "Arthrex"). Specifically, Mitek moves to exclude Mr. Witherspoon's (1) legal conclusions that Arthrex does not infringe Mitek's patent; and (2) his recitation of the applicable patent laws.[1] Mr. Witherspoon proposes to play the role of both judge -- by instructing the jury as to controlling law -- and jury -- by applying the law as he pronounces it to the facts. There are numerous reasons for excluding Mr. Witherspoon's proposed testimony.

[1] Mitek is specifically seeking to preclude Mr. Witherspoon from testifying about the subject matter in paragraphs 1-12, 15-19 of his March 24, 2007 expert report.

First, Mr. Witherspoon, a *patent lawyer*, is admittedly not qualified under FED. R. EVID. 702 by either knowledge, skill, training, or experience to testify to the technical subject matter of infringement. Nonetheless, Arthrex proposes to call Mr. Witherspoon to offer opinions on infringement. Furthermore, his testimony will not assist the trier of fact because he simply restates the conclusions of another Arthrex *technical* expert. Mr. Witherspoon's opinions of no infringement should be excluded under FED. R. EVID. 702, 402, and 403.

Second, Mr. Witherspoon's proposed testimony regarding the applicable laws of infringement should be excluded because it invades the province of the Court and will confuse the jury. Mr. Witherspoon's proposed testimony in this area will not assist the Court or the jury, will be irrelevant, will confuse the issues, waste time, and cause undue delay and should be excluded under FED. R. EVID. 402, 403 and 702.

I. MR. WITHERSPOON'S PROPOSED TESTIMONY

Mr. Witherspoon submitted three expert reports on behalf of Arthrex (Exs. 1-3). While Mr. Witherspoon's expert reports contain numerous opinions,[2] the only ones Mitek wishes to exclude at this time are Mr. Witherspoon's:

A.. opinions of no infringement; and

B. recitation of the applicable patent laws.

(Ex. 2 at ¶¶1-12 & 15-19). Mitek will address each of these two areas of proposed testimony below and the reasons such testimony should be excluded.

[2] For example, Mr. Witherspoon also opines on patent validity and willful infringement issues. (See Exs. 1 & 2). Those issues are not being tried in the upcoming August trial.

II. MR. WITHERSPOON'S PROPOSED TESTIMONY SHOULD BE EXCLUDED ON NUMEROUS GROUNDS

A. Mr. Witherspoon's Opinion Of No Infringement Should Be Excluded Under FED. R. EVID. 702 And 403

Mr. Witherspoon concludes that Arthrex does not infringe Mitek's patent for a variety of reasons (See Ex. 2 at ¶¶ 16-19). For example, Mr. Witherspoon concludes in his report:

> 17. As I explained above, the language "consisting essentially of" excludes the presence of a non-recited component which materially affects the basic and novel characteristics of the invention. I understand that the coating on FiberWire, TigerWire and FiberStick is such a component, and for this additional reason these products do not infringe. Further, I understand that the nylon in TigerWire is such a component, and constitutes yet another reason as to why this product does not infringe. Finally, I understand that the adhesive on FiberStick is such a component, and constitutes yet another reason as to why this product does not infringe. ***My opinions in this regard are based upon the expected testimony of Dr. Mukherjee, as set forth in his report***. (Ex. 2 at ¶17, emphasis added)

According to his Responsive Expert Report, Dr. Mukherjee plans to testify that the coating on FiberWire materially affects the basic and novel properties of the suture (Ex. 8 at 22). Mr. Witherspoon's proposed "no infringement" testimony should be excluded under Rule 702 because it is not based upon "specialized knowledge" that will assist the trier of fact to understand the evidence. The *only* basis for Mr. Witherspoon's conclusion of no infringement is an "understanding" from Dr. Mukherjee. Mr. Witherspoon is a patent lawyer and admitted that he is not a person of ordinary skill in the art to which the patent pertains (Ex. 4 at 32). But infringement analysis involves determination of the meaning of the claims according to a person of ordinary skill in the art. *Ranbaxy Pharms., Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1239-1240 (Fed. Cir. 2003); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-1315 (Fed. Cir. 2005). He is in no position to opine on the credibility or validity of Dr. Mukherjee's technical conclusions. Yet, if he is allowed to testify that, based on Dr. Mukherjee's testimony, he concludes there is no infringement, he is effectively endorsing Dr. Mukherjee's conclusions. His testimony is

designed to tell jurors what to decide, rather than to help them understand relevant information. This proposed testimony is not helpful to the jury. It is essentially attorney argument in the guise of expert testimony and should be excluded under Rule 702. *P&G v. Teva Pharms. USA, Inc.*, No. 04-940-JJF, 2006 U.S. Dist. LEXIS 54260, at *4 (D. Del. Aug. 4, 2006)(precluding patent law expert from "legal conclusions or substantive issues of patent law") (Ex. 5).

Further, Mr. Witherspoon's legal conclusion of no infringement should be excluded under Rule 403 because it would be highly prejudicial, accepting that it even has some marginal relevance. Given that Arthrex will undoubtedly recite for the jury that Mr. Witherspoon is a former Examiner-in-Chief and a member of the then Board of Appeals of the Patent and Trademark Office, there is a substantial risk that jurors would defer to his conclusion, rather than undertake their own independent analysis. This testimony should therefore be precluded under FED. R. EVID. 403.

Mitek is entitled to have the *jury* apply the law to the facts to reach its own decision on infringement. Because Mr. Witherspoon's testimony will suggest to the jury how it should apply the law to the facts, and what conclusion it should reach, it is improper and highly prejudicial and should be excluded under FED. R. EVID. 702 and 403.

B. Mr. Witherspoon's Recitation Of Applicable Patent Law Should Be Excluded Under FED. R. EVID. 403 And 702

Mr. Witherspoon also proposes to recite the applicable patent law (*See* Ex. 2 at ¶¶1-12). Specifically, Mr. Witherspoon proposes to instruct the jury as to the controlling law on literal infringement, reverse doctrine of equivalents, direct and indirect infringement and the legal significance of the "consisting essentially of" language (*id.* at ¶¶1-3, 7-8 and 10). For example, Mr. Witherspoon says:

> 2. Determining infringement entails a two-step analysis-first, a claim must be construed and then the properly construed claim is compared with the accused

> product. With respect to the first step, a claim must be interpreted in light of its language, other claims in the patent, the specification of the patent, and the prosecution history of the patent. Interpreting a claim in light of the specification should be distinguished from reading a limitation from the specification into the claim. That is, the specification can be used to interpret the meaning of terms in a claim, but cannot be used to read a limitation into the claim. The scope of a claim is normally not limited to the specific embodiment or embodiments disclosed in the specification and drawings. The prosecution history also may affect the meaning of a term in a claim. A claim must be interpreted the same way for purposes of validity and for purposes of infringement. (*id.* at ¶2).

This, and other proposed "legal" testimony from Mr. Witherspoon's report reads like a jury instruction. To the extent he proposes to instruct the jury as to his view of the controlling patent law, Mr. Witherspoon's testimony should be excluded. "It is black-letter law that 'it is not for witnesses to instruct the jury as to applicable principles of law, but for the judge.'" *Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92, 99 (1st Cir. 1997) (quoting *United States v. Newman*, 49 F.3d 1, 7 (1st Cir. 1995)) Mr. Witherspoon should not be permitted to compete with the Court in instructing the jury as to applicable law.[3]

In fact, Mr. Witherspoon has had other "legal" testimony previously precluded. *Revlon Consumer Prods. Corp. v. L'oreal S.A., Cosmair, Inc.*, C.A. No. 96-192 MMS, 1997 U.S. Dist. LEXIS 4117 (D. Del. Mar. 26, 1997) (The "Court . . . cannot permit Mr. Witherspoon to testify

[3] *Marx & Co., Inc. v. Diners' Club*, 550 F.2d 505, 509-510 (2d Cir. 1977)("It is not for witnesses to instruct the jury as to applicable principles of law, but for the judge."); *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 2006 U.S. Dist. LEXIS 77966 (D.N.J. Oct. 26, 2006)(precluding patent law expert's "testimony to the extent he plans to testify as to general principles of patent law or to offer legal opinions.") (Ex. 6); *P&G v. Teva Pharms. USA, Inc.*, 2006 U.S. Dist. LEXIS 54260 (D. Del. Aug. 4, 2006)(precluding patent law expert from "legal conclusions or substantive issues of patent law") (Ex. 5); *Burkhart v. Washington Metro. Area Transit Auth.*, 112 F.3d 1207, 1213 (D.C. Cir. 1997)("Each courtroom comes equipped with a "legal expert," called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards."); *Nutrition 21 v. United States*, 930 F.2d 867, 871 n.2, 18 U.S.P.Q.2D (BNA) 1347, 1350 n.2 (Fed. Cir. 1991) (patent law expert's "opinion on the ultimate legal conclusion is neither required nor indeed 'evidence' at all").

as an expert on inequitable conduct; to do otherwise would usurp the respective functions of the jury and the Court.") (Ex. 7).

Mr. Witherspoon's recitation of the applicable law is inappropriate and should be excluded under FED. R. EVID. 402, 403, and 702 because it will mislead the jury and be a waste time.

III. ARTHREX WILL NOT BE PREJUDICED IF PORTIONS OF MR. WITHERSPOON'S TESTIMONY ARE EXCLUDED

Arthrex will not be prejudiced if Mr. Witherspoon's "no infringement" testimony is excluded. The underlying facts of infringement will undoubtedly be presented to the jury, and the Court will instruct the jury on the applicable law. Arthrex's counsel can put the facts into perspective in closing argument. This will allow the jury to do what *it* is supposed to do -- which is to reach its own conclusions regarding infringement.

It would be improper to allow a lawyer-expert to offer a conclusion that was spoon-fed by Arthrex's lawyers and its other technical experts and then merely regurgitate that conclusion to the jury. The proposed testimony has little, if any, probative value. Even if it were otherwise proper, the testimony should nonetheless be excluded because the danger of unfair prejudice to Mitek far outweighs any potential probative value.

IV. CONCLUSION

For the foregoing reasons, Mitek requests that the Court enter an order excluding Mr. Witherspoon from testifying about conclusions of infringement and the applicable patent law.

Dated: July 13, 2007

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CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

Plaintiff DePuy Mitek's Motion *In Limine* (No. 4) To Limit the Testimony of Arthrex's Patent Law Expert, Mr. Witherspoon; and

Plaintiff DePuy Mitek's Memorandum In Support Of Motion *In Limine* (No. 4) To Limit The Testimony Of Arthrex's Patent Law Expert, Mr. Witherspoon

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

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EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	Civil Action No. 04-12457 PBS

EXPERT REPORT OF JOHN F. WITHERSPOON

INTRODUCTION

I have been asked by counsel for defendant Arthrex, Inc. ("Arthrex") to serve as an expert consultant with respect to United States patent practices and procedures, both generally and as they relate to this case, and on various issues in the case. I understand that I may be called to present expert testimony at trial, including testimony in rebuttal, and I have been asked to prepare a written report with respect to that possible testimony. More specifically, I have been asked at this time to prepare a report setting forth (a) a general description of United States Patent and Trademark Office ("PTO") practices and procedures, (b) a discussion of the prosecution history of United States Patent No. 5,314,446 ("the '446 patent") here in suit, and (c) opinions specific to this case regarding certain issues for which Arthrex has the burden of proof.

I reserve the right to file a report in rebuttal to those filed on behalf of the plaintiff. I also reserve the right to supplement my report(s) so as to accommodate the discovery of any additional information that may impact my testimony and opinions.

BACKGROUND AND PROFESSIONAL EXPERIENCE

1. I am a citizen of the United States and reside in Bethesda, Maryland.

2. I am an attorney in private practice in Washington, D.C., where I have practiced patent law for over thirty years. In addition, I served as an Examiner-in-Chief (a position now called "Administrative Patent Judge") and as a member of the Board of Appeals (now named the Board of Patent Appeals and Interferences) in the PTO for seven and one-half years. Before entering private practice, I served for two years as a Law Clerk to Judge Giles Sutherland Rich of the United States Court of Customs and Patent Appeals ("CCPA") a predecessor court to the United States Court of Appeals for the Federal Circuit ("Federal Circuit").

3. From 1992-2004, I was Distinguished Professor of Intellectual Property Law and Coordinator or Co-Director of the specialty track in Intellectual Property Law at George Mason University School of Law in Arlington, Virginia, where I was a member of the part-time faculty and taught courses in patent law. In recognition of this work the law school faculty and University Provost unanimously voted to accord me the title "Professor and Director Emeritus, Intellectual Property Program, George Mason University School of Law." From 1998-2000, I also served as an Adjunct Professor of Law at the Georgetown University Law Center in Washington, D.C.

4. I was nominated by the President of the United States and confirmed by the Senate to be an Examiner-in-Chief and a member of the then Board of Appeals of the

PTO. The Board of Appeals is a review tribunal within the PTO that by statute sits in panels of at least three members to hear appeals from adverse decisions of examiners. It reviews the record made during the examination of an application, receives briefs from counsel and examiners, conducts hearings, and prepares written opinions. The Board's decisions constitute final agency determinations with respect to substantive questions of patent law. They are reviewable only by the Federal Circuit or by the United States District Court for the District of Columbia, whose decisions in such cases are in turn reviewable by the Federal Circuit. My work as a member of the Board of Appeals required an understanding of patent specifications, including patent claims and how they should be construed, as well as an understanding and application of the pertinent statutes, precedents, rules, and other regulations regarding the requirements for patentability and the examination of patent applications for issuance of United States letters patents. While on the Board, I participated in deciding more than 1,500 appeals.

5. During my career in private practice, I have personally prosecuted hundreds of applications for patents and reviewed hundreds of prosecution histories of other applications. As part of this work, I have had occasion to review thousands of claims in patents and patent applications to determine their meaning, to compare them with the prior art and other claims, to compare them with patent specifications, or to compare them with accused products, processes, etc. For the past twenty-five years I have also served as a consulting and/or testifying expert in patent litigation.

6. I am admitted to practice law in the District of Columbia and before the Supreme Court of the United States, the United States Court of Appeals for the District of

Columbia Circuit and the United States Court of Appeals for the Federal Circuit. I am also registered to practice before the PTO.

7. I am a member of numerous bar associations and professional societies relating to patent law and to science, including the American Bar Association Section of Intellectual Property Law, the American Intellectual Property Law Association, the Federal Circuit Bar Association, the Patent and Trademark Office Society, the Giles Sutherland Rich American Inn of Court, the New York Intellectual Property Law Association, the American Association for the Advancement of Science, and the American Chemical Society. Over the years I have held leadership positions in a number of these organizations.

8. I have been a member of the Advisory Board of BNA's Patent, Trademark and Copyright Journal since 1979. I am the editor of a book by BNA entitled "Nonobviousness—The Ultimate Condition of Patentability," and I have written several published articles in the field of United States patent law and practice. In addition, I have presented lectures and speeches about United States patent law and practice throughout the United States and Europe, including to the Judicial Conferences of the CCPA and the Federal Circuit.

9. I did undergraduate and graduate studies at the University of Illinois, receiving a B.S. degree in 1955, an M.Ed. degree in 1958, and an M.S. degree in Chemistry in 1960. I received an L.L.B. degree (later changed to a J.D. degree) from Georgetown University Law Center in 1964.

10. A copy of my Curriculum Vitae, which lists my publications, and a listing of cases in which I have testified in the past four years are attached as Exhibits A and B, respectively.

DATA AND OTHER INFORMATION CONSIDERED

11. In preparing this report, I reviewed the following materials:

a) U.S. Patent No. 5,314,446 in the names of Alastair W. Hunter, Arthur Taylor, Jr. and Mark Steckel ("the '446 patent");

b) Prosecution history of the '446 patent;

c) U.S. Patent Nos. 4,543,286 ("Harpell *et al.* '286"); 4,563,392 ("Harpell *et al.* '392"); 4,610,688 ("Silvestrini *et al.*"); 5,120,802 ("Mares *et al.*"); and 5,318,575 ("Chesterfield *et al.*");

d) U.K. Patent Application 2 218 312 A ("Burgess");

e) Brochure designated Dyneema SK60 ("the Dyneema brochure") (Bates Nos. PR 08420-429);

f) Article by Cohan *et al.* entitled "An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture" ("Cohan *et al.*") (Bates Nos. ARM 25132-137);

g) DePuy Mitek's Responses to Arthrex, Inc.'s First Set of Interrogatories; DePuy Mitek's Supplemental Responses to Arthrex, Inc.'s First Set of Interrogatories; DePuy Mitek's Responses to Arthrex, Inc.'s Second Set of Interrogatories; DePuy Mitek's Second Supplemental Responses to Arthrex, Inc.'s First Set of Interrogatories; and DePuy Mitek's Second Supplemental Responses to Arthrex, Inc.'s Interrogatory No. 15;

h) Arthrex, Inc.'s Objections and Answers to DePuy Mitek, Inc.'s First Set of Interrogatories; Arthrex, Inc.'s Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 2, 4, 10 and 12; Arthrex, Inc.'s Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 3, 5 and 7; Arthrex, Inc.'s Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 1; Arthrex, Inc.'s Second Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogtory Nos. 3, 5, and 7 and Arthrex's Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 6; Arthrex, Inc.'s Objections and Response to DePuy Mitek, Inc.'s Second Set of Interrogatories to Arthrex, Inc.; and Pearsalls, Limited's

Objections and Response to DePuy Mitek, Inc.'s Second Set of Interrogatories to Pearsalls, Limited;

i) Transcripts of depositions of Dr. Mark G. Steckel given on January 26 and January 27, 2006; Dennis J. Jamiolkowski given on November 30, 2005; Hal Brent Woodrow given on November 2, 2005; and Matthew Goodwin given on January 17, 2006;

j) Portions of laboratory Book No. 2175, issued to Mark Steckel (Bates Nos. DMI002605-2678);

k) Documents bearing Bates Nos. DMI095015-5042;

l) Five page document entitled DePuy Mitek's Privileged Document List, dated January 23, 2006;

m) Discussion with Dr. Debi Prasad Mukherjee; and

n) Expert Report of Dr. Debi Prasad Mukherjee Concerning Invalidity of U.S. Patent No. 5,314,446.

BASES FOR TESTIMONY AND OPINIONS

12. The bases for my testimony and opinions are the materials identified above; my background, training, and over forty-three years of working experience in the field of patent law and practice, including my knowledge of and experience with the practices and procedures of the PTO, acquired in part during the more than seven years that I served as a member of the PTO Board of Appeals; the patent statutes; case decisions; the PTO rules of practice as set forth in Title 37 of the Code of Federal Regulations (37 CFR); and the PTO Manual of Patent Examining Procedure ("MPEP"). My testimony may also be based, in part, on the testimony and discussions with other witnesses (both expert and fact) and associated documentation in this case.

GENERAL CONSIDERATIONS

The Parts of Patent Applications and Patents

13. A patent is a legal document issued by the federal government that reflects a kind of bargain between an inventor and the public. The inventor must have made an invention that satisfies certain legal requirements and must disclose the invention in accordance with certain legal standards. The public, in turn, grants to the patent owner the right to exclude others from practicing the invention during the term of the patent. Contrary to popular belief, a patent does not grant to the patent owner the right to practice the invention.

14. Patents are directed to one of four statutory classes of subject matter that qualifies for patent protection—(1) process, (2) machine, (3) manufacture, and (4) composition of matter. Thus, also contrary to popular belief, patents do not protect concepts or ideas. Rather, they pertain to the "useful arts"—the term used in the Constitution.

15. A patent or patent application consists of two main parts: a "written description" and one or more "claims." The two parts constitute the *quid* and the *quo* of the bargain.

16. The written description, sometimes called the specification, explains what the invention is, how it is made, how it is used, and the best mode of carrying out the invention, all in sufficient detail that the public (*i.e.,* persons skilled in the art to which the invention pertains) is able to understand and practice the invention without undue experimentation. Drawings, charts and/or graphs are often used to help explain what is

being described. The "written description" part of a patent is basically a teaching document. Its purpose is to satisfy the inventor's part of the bargain with the public.

17. In contrast, the claims of a patent are legal instruments that define the scope of the patent owner's exclusive rights. Each claim is a separate instrument. It is a single sentence comprising a list of words and phrases (known as claim "elements" or "limitations") which together make up the claim. A claim must be reviewed in its entirety or, as is sometimes said, "as a whole." Every patent must have at least one claim. Claims appear at the very end of the patent and, if there is more than one, the claims are numbered. According to the Supreme Court, the construction of a patent, "including terms of art within its claims," is exclusively within the province of the court.

18. A more detailed discussion of claims is set forth in Exhibit C.

The Examination of Patent Applications in the PTO

19. The PTO is an agency within the United States Department of Commerce. It is physically located in Alexandria, Virginia. It is fully funded by fees paid by its users, including applicants for patents and owners of issued patents. The principal responsibility of the PTO with respect to its patent operation is to examine patent applications to determine whether they should issue as patents. The governing authorities, in decreasing order of importance, are the statutory provisions set forth in Title 35 of the United States Code (35 USC), court decisions, the codified Patent Rules of Practice set forth in Title 37 of the Code of Federal Regulations (37 CFR), and the Manual of Patent Examining Procedure (MPEP), which sets forth additional guidelines and instructions to examiners.

20. The PTO currently employs about 4000 patent examiners, each of whom is assigned to a particular class or specialty of technology corresponding to the individual

examiner's science or engineering degree and/or work experience, if any. Generally speaking, examiners have an undergraduate degree (a limited number having an advanced degree) in some field of science or engineering, but little or no actual experience working in the field. They are therefore normally not persons skilled in the art to which they are assigned. However, they are assumed to have some expertise in interpreting prior art references and to be familiar from their work with the level of skill in the art. The patent applications on an examiner's docket normally fall within the subclass or specialties assigned to that examiner. Some examiners are lawyers, but many are not.

21. In examining a patent application an examiner is expected first to obtain an understanding of the application and claimed invention and then search the most relevant prior art available to the examiner. The "prior art" under United States law is very extensive. It includes all patents throughout the world, all printed publications throughout the world (which may include electronic publications and websites), and all prior public use activity, on sale activity, public knowledge by others, and inventions by others in the United States.

22. Prior art in the form of trade literature, sales brochures, some scientific publications, and some foreign patents are generally not available to examiners. The same is true with respect to prior public knowledge, prior public uses, prior sales and offers for sale of products in commerce, and prior inventions of others. Examiners do not have the benefit of technical experts or other workers in the field with whom to consult. Nor do examiners have the benefit of laboratories with which to carry out experiments to verify the accuracy and completeness of statements made in a patent specification, in affidavits and declarations, and in arguments made during prosecution of the application.

23. The examination of patent applications is *ex parte* in nature; the public does not participate. Historically, patent applications and their examinations (subject to a few limited exceptions) were required by statute to be kept in confidence. (Legislation enacted in 1999 now provides for the automatic publication of many applications after eighteen months.) Generally speaking, each examiner has many (typically over a hundred) patent applications on his or her docket at any given time, and therefore has a limited time to devote to each patent application.

24. The examination of an application in the PTO usually entails a multi-stage process of submission, rejection by the examiner accompanied by commentary explaining the reasons for the rejection, response by the applicant, etc. An applicant's response often entails amending claims to narrow their scope in an attempt to avoid prior art. Applicants also frequently present arguments as to why their claims are patentable over the prior art. Evidence in the form of an affidavit or declaration is sometimes submitted by the applicant.

25. PTO regulations permit interviews between examiners and applicants, their attorneys or agents. Such interviews may be in person in an examiner's office or by telephone.

26. The exchanges between an applicant and the examiner constitute what is called "patent prosecution." Historically, the patent prosecution papers have been maintained in the PTO in a folder called a "file wrapper". In recent times an electronic copy of these papers, as well as an electronic copy of the application papers themselves, make up what is called an "image file wrapper" or IFW. In either case, these materials constitute the official record of a patent's history. The prosecution history may be an important instrument in determining the scope of an issued patent.

27. 37 CFR § 1.56 (1992), commonly referred to as PTO "Rule 56," reads in part as follows:

> § 1.56 Duty to disclose information material to patentability.
>
> (a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section…

28. Examiners expect and rely on inventors and their attorneys or agents to be truthful and to act with candor and good faith in dealing with the PTO, as required by the PTO regulations and case decisions. The duty applies to all individuals associated with the filing or prosecution of an application. These individuals have a duty to disclose information known to one or more of them to be material to patentability. Examiners expect and rely on them to comply with this duty. There are several reasons for these expectations. First, as discussed above, an examiner does not have access to all prior art. Nor does an examiner have an opportunity to verify the accuracy of representations of fact known only by the inventor. Second, an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, may mislead an examiner into granting a patent which does not meet the legal criteria. The duty of disclosure includes a duty to tell an examiner of an erroneous material representation, when discovered, during PTO proceeding.

29. Normally material prior art is called to an examiner's attention by filing a document known as an Information Disclosure Statement ("IDS"). However, such

information may also be called to an examiner's attention in the remarks section of a response to an Office Action or in the patent application itself.

30. Prior to March 16, 1992, Rule 56 defined material information as information as to which there is a substantial likelihood a reasonable examiner would consider the information important in deciding whether to allow the application. Since March 16, 1992, Rule 56 has provided that information is material when it is not cumulative to information already of record and (1) establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) refutes, or is inconsistent with, a position the applicant takes in either opposing an argument of unpatentability or asserting an argument of patentability.

31. The MPEP is an official publication of the PTO that is intended to provide patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the PTO. Section 2004, entitled "Aids to Compliance With Duty of Disclosure" sets forth suggestions for complying with the duty of disclosure. Among things to be considered are: "the origin of the invention and its point of departure from what was previously known and in the prior art;" "possible public uses and sales;" and "prior publication, knowledge, patents, foreign patents, etc." Section 2004 also emphasizes that "[c]are should be taken to see that prior art or other information cited in a specification or an information disclosure statement is properly described and that the information is not incorrectly or incompletely characterized." It is further pointed out that "[w]hen in doubt, it is desirable and safest to submit information," since "[e]ven though the attorney, agent, or applicant doesn't consider it necessarily material, someone

else may see it differently and embarrassing questions can be avoided." In this regard, the Manual points out that one district court has stated: "In short, the question of relevancy in close cases, should be left to the examiner and not the applicant." The Manual also notes that "[i]t may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention." Thus the MPEP strongly suggests erring on the side of disclosure. (The quoted passages from the MPEP appeared in the Manual throughout the pendency of the application leading to the '446 patent.)

32. The duty of inventors and their attorneys or agents to disclose material information is a continuing duty that runs throughout the entire pendency of a patent application.

33. In reviewing an application, an examiner is expected to determine whether the specification contains a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which the invention pertains to make and use the invention without undue experimentation. To the extent possible, he or she also reviews the application to see whether the best mode contemplated by the inventor of carrying out her invention is disclosed. These requirements are sometimes called (1) the "written description" requirement, (2) the "enablement" requirement, and (3) the "best mode" requirement.

34. An examiner is expected to understand that the test for the written description requirement is whether the disclosure of the application reasonably conveys to one skilled in the art that the inventor had possession of the claimed subject matter at the time the application was filed and that the test for the enablement requirement is whether the

specification, viewed from the perspective of a person skilled in the art, teaches such a person how to make and use the claimed subject matter without having to resort to undue experimentation.

35. In determining compliance with the "written description" and "enablement" requirements, an examiner is expected to understand that a broad or generic term found in a specification does not necessarily cover any and all technology that might otherwise seem to be embraced by the term. One must also consider the context in which the term is used. For example, if the specification indicates that the technology designated by the term must possess certain characteristics or properties, then things that do not possess those characteristics or properties should not be deemed to be "described" or "enabled" simply because the term is used.

36. An examiner is expected to determine whether a patent specification concludes with one or more claims which particularly point out and distinctly claim the subject matter that the applicant regards as his invention. This requirement is sometimes called the requirement for "definiteness". In doing so, an examiner is expected to consider that a claim should set out and circumscribe a particular area with a reasonable degree of precision and particularity. The definiteness of claim language must be analyzed in light of the teachings of the prior art and of the disclosure in the specification as it would be interpreted by a person possessing the ordinary level of skill in the pertinent art. An examiner would be expected to understand that the principal sources for construing claims is the language of the claim and the disclosures of the specification, and that transitional terms such as "comprising", "consisting of", and "consisting essentially of" should be construed according to their well-established meanings in the law.

37. An examiner is expected to determine whether a claim is directed to subject matter that is new relative to the prior art. In doing so, an examiner is expected to recognize that a claim is not directed to new subject matter if a single item of prior art anticipates, *i.e.*, identically discloses each element of the claimed invention in the claimed relationship.

38. An examiner is expected to determine whether a claim is directed to subject matter that, although novel, satisfies the requirement for nonobviousness. In doing so, an examiner is expected to consider the level of skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed invention. Against this background, the examiner is expected to determine whether the subject matter of the claim as a whole would have been nonobvious to a person having ordinary skill in the art at the time the invention was made. Any "secondary" consideration evidence submitted by an applicant must be taken into account. Such evidence is sometimes presented in a declaration or affidavit. Examples of secondary considerations indicative of the nonobviousness of a claimed invention are long felt need, prior attempts and failures, acceptance by others, including copying, simultaneous developments, and commercial success. The results achieved by an invention may also constitute evidence of nonobviousness if they are unexpected, *i.e.*, not taught or suggested by the prior art.

39. An examiner is expected to understand that prior art documents are deemed to be addressed to persons of ordinary skill in the pertinent art, and that for purposes of evaluating nonobviousness issues, a prior art document should be considered from the standpoint of what it teaches or suggests to one having the knowledge of a person of ordinary skill in the art. Obviousness is to be determined as of the time the invention was made or one year prior to the filing date. An examiner is also expected to understand that

a conclusion of obviousness cannot properly be made unless the state of the art is such as to provide a motivation or reason for the person of ordinary skill to combine the teachings of the prior art.

40. The practice of combining the teachings of two or more prior art "references" can be illustrated as follows: Suppose an examiner is reviewing a patent application claiming a chair that has rollers. The examiner finds a prior patent or printed publication that discloses a chair without rollers. The examiner finds another prior patent or printed publication that discloses a piano that has rollers and explains that the rollers make the piano easier to move. The examiner rejects the claim before her as not being in compliance with the requirement for nonobviousness. In doing so, the examiner reasons that it would have been obvious to a person of ordinary skill in the furniture art, in view of the combined teachings of the two references (which the hypothetical person of ordinary skill in the art is presumed to know), to modify the prior art chair by making it with rollers, and that when so modified one obtains the subject matter being claimed. The examiner also explains that the motivation or reason for modifying the prior art chair in this manner is provided by the knowledge of the person having ordinary skill that rollers make the piano easier to move. Indeed, in this simple example the examiner alternatively might reason that one skilled in the art would be motivated to modify the prior art chair by making it with rollers, because rollers are well known generally to workers in the art (even to lay people) to make things such as furniture easier to move; however, the piano reference reinforces this contention considerably.

41. Since the examination of a United States patent application is an *ex parte* proceeding, an examiner need only establish a *prima facie* case of obviousness in order to

shift the burden of going forward to the applicant. In his response, an applicant may challenge whether a *prima facie* case has been established or, alternatively, attempt to overcome the *prima facie* case by submitting evidence in affidavit or declaration form which purports to demonstrate nonobviousness of the claimed subject matter. This evidence may include test data or experimental results obtained from a comparison of the claimed subject matter with the prior art. All relevant data must be disclosed. It is not proper to submit to the PTO only favorable results and withhold unfavorable results because to do so would be misleading.

42. An examiner is expected to understand that under certain circumstances an applicant is entitled to bring forward evidence (in the form of declarations or affidavits) establishing a date of invention prior to the application's filing date, and thereby overcome (*i.e.*, antedate) one or more prior art references. This may be done by proving a conception and an actual reduction to practice of the claimed invention prior to the effective date of the reference. The determination of the date of an invention is claim specific. Conception is defined as the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice. Normally the only corroboration required is of the formation of the idea or concept by the inventor. The invention is regarded to have been actually reduced to practice when the concept has been embodied in some physical form that contains every limitation of a claim and that is demonstrated to be a workable embodiment. In some instances, laboratory testing of a physical embodiment may be sufficient to demonstrate its workability for its intended purpose or use. In other instances, testing under commercial or actual conditions of intended use may be required to establish actual reduction to practice. Normally

corroboration must be provided in the form of direct or circumstantial evidence that the embodiment of the invention was constructed and was demonstrated to work successfully. This can include testimony of a co-employee with first hand knowledge of the work done. Conception determines "who" made the invention and controls the question of inventorship, whereas reduction to practice determines "when" the invention was made.

TESTIMONY SPECIFIC TO THIS CASE

Preliminary Remarks

43. I understand that the claims of the '446 patent being asserted in this litigation are independent claim 1 and dependent claims 2, 8 and 12 ("the asserted claims"). I also understand that the parties disagree as to the meaning of the term "PE" that appears, directly or indirectly, in all of the asserted claims. More specifically, I understand that the parties disagree as to whether ultra high molecular weight polyethylene ("UHMWPE") is within the scope of the claims. Finally, I understand that the Court has yet to resolve this dispute.

Prosecution History

44. I expect to explain the prosecution history of the '446 patent. More specifically, I expect to testify regarding the events that occurred during the prosecution by identifying and discussing in varying degrees certain of the papers appearing in the file history. More specifically yet, I expect to explain what prior art and other information was and was not considered by the examiner, what objections, rejections and statements were made by the examiner, and what responses and amendments were made by the applicants. This testimony would be essentially descriptive and explanatory in nature, and include at least some of the following points.

45. On February 19, 1992, an application for patent entitled "Sterilized Heterogeneous Braids" was filed in the PTO in the names of Alastair W. Hunter, Dennis D. Jamiolkowski, Arthur Taylor, Jr. and Mark Steckel. It was assigned application No. 07/838,511. It contained three sheets of drawings, which included three Figures. It contained twenty-four claims, claims 1-20 being directed to a "heterogeneous braid" and claims 21-24 being directed to a "surgical suture."

46. The Declaration accompanying the application and which was signed by the four named inventors contains the following statements:

> I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.
>
> I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

47. On the same day, an Information Disclosure Statement was filed which identified eleven references, five of which were said by Mr. Goodwin to have been discussed in the Background of the Invention. Mr. Goodwin also stated that the additional six references "may be relevant" to the examination of the application. In doing so, he had this to say with respect to one of them:

> U.K. Patent Application GB 2 218 312A [Burgess], discloses a fishing line of braided construction, some braid filaments being composed of polythene and other filaments composed of polyester and/or nylon.

48. On July 8, 1992, the examiner required restriction between "claims 1-20, drawn to a heterogeneous braid" and "claims 21-24, drawn to a surgical suture," saying that the two groups of claims "are related as mutually exclusive species in intermediate-final product relationship." The examiner explained that distinctness "is proven for

claims in this relationship if the intermediate product is useful to make other than the final product...and the species are patentably distinct...." Further, the examiner explained that "in the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants." In a telephone conversation, Mr. Goodwin made a provisional election of claims 21-24, *i.e.,* the claims drawn to a surgical suture.

49. In the same Office Action, the examiner rejected claims 21-24 under 35 U.S.C. 103 as being unpatentable over Burgess. On August 6, 1992, Mr. Goodwin mailed a response to the PTO in which he sought to refute the examiner's rejection and underlying reasoning.

50. In the next Office Action, dated November 2, 1992, the examiner dropped his rejection based on Burgess. In responding to the Office Action, on December 2, 1992, Mr. Goodwin stated that:

> Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

51. On March 18, 1993, the examiner continued to reject all claims, but not on Burgess. On August 4, 1993, a new attorney, Mr. Woodrow, mailed to the PTO an Amendment in which application claim 21 was amended. Amended claim 21 became claim 1 of the '446 patent. On the same day, Mr. Woodrow mailed an IDS. The IDS called the examiner's attention to five U.S. patents and one British patent.

52. The application was allowed on November 18, 1993, and it issued on May 24, 1994 as the '446 patent.

Specific Opinions and Conclusions

53. Based upon my study of this case to date, I have formed the following opinions and reached the following conclusions.

54. If the term "PE" in the asserted claims of the '446 patent is construed by the Court to include ultra high molecular weight polyethylene ("UHMWPE"), then they are invalid for failing to satisfy the written description and enablement requirements of the first paragraph of 35 U.S.C. 112. (Since dependent claims 2, 8 and 12 do not limit claim 1 with respect to the term PE, they are subject to the same claim construction and are invalid under this claim construction for the same reasons that apply to claim 1.) The bases for my opinion include the principles set forth in paragraphs 33-35, *supra,* and the expected testimony of Dr. Mukherjee as set forth in his Report.

55. If the term "PE" in the asserted claims of the '446 patent is construed by the Court to include UHMWPE, then they are invalid for failing to satisfy the novelty requirement because they are anticipated by Chesterfield *et al.* I understand that the plaintiff contends that the invention of the '446 patent was reduced to practice "at least as early as February 2, 1989" (Supp. Resp. to Int. No. 6) *i.e.,* three years before the February 3, 1992 filing date of Chesterfield *et al.* I disagree. I find no evidence that a "surgical suture," as required by each asserted claim, was constructed. I find no evidence that "a sterilized, braided construction," as required by each asserted claim, was built before the effective date of the reference. Furthermore, the braided structures that were built appear to have experienced substantial problems with core popping and braid

looseness. And in a handwritten note dated February 9, 1990, Dr. Schwartz specifically referred to "technical problems of mixing 2 materials with dissimilar stress/strain properties." (Bates No. DMI095020.) This notation is entirely consistent with the fact that I have seen no evidence indicating that these problems had been solved prior to February 2, 1989. Nor have I seen evidence that they had been solved prior to the February 19, 1992 filing date of the '446 patent. Under the circumstances, Chesterfield *et al.* is a prior art reference under 35 U.S.C. 102(e). The bases for my opinion include the principles set forth in paragraphs 37 and 42, *supra,* and the expected testimony of Dr. Mukherjee as set forth in his Report both with respect to the disclosure of Chesterfield *et al.* and the lack of proof of a reduction to practice.

56. If the term "PE" in the asserted claims of the '446 patent is construed by the Court to include UMHWPE, then they are invalid for failing to satisfy the nonobviouness requirement of 35 U.S.C. 103 in view of the following prior art references: Burgess, the Dyneema brochure, the Cohan *et al.* article, and Harpell *et al.* '286 and '392. The bases for my opinion include the principles set forth in paragraphs 38-40, *supra,* and the expected testimony of Dr. Mukherjee as set forth in his Report.

57. Regardless of whether the Court construes the term PE to include UHMWPE, I would expect to testify that the asserted claims are invalid for failing to satisfy the nonobviousness requirement of 35 U.S.C. 103 in view of Silvestrini *et al* and the '802 patent to Mares *et al.* The bases for my opinion include the principles set forth in paragraphs 38-40, *supra,* and the expected testimony of Dr. Mukherjee as set forth in his Report.

58. If the term "PE" in the asserted claims of the '446 patent is construed by the Court to include UMHWPE, then I would expect to testify that Dr. Steckel, and Mr. Hunter, and/or Mr. Goodwin may have violated their duty to disclose material information to the PTO, as required by Rule 56. The bases for my opinion include the principles set forth in paragraphs 27-32, *supra,* the deposition testimony of Dr. Steckel, the deposition testimony of Mr. Goodwin, the arguments by Mr. Goodwin in his response mailed on August 6, 1992, as set forth in paragraph 49, *supra*, and the January 23, 2006 privileged document list. A more specific discussion is set forth below.

59. According to Dr. Steckel, he and at least co-inventor Hunter conceived of a braid construction made up of two dissimilar materials for use as a surgical suture, and that one such construction that they contemplated was the combination of UHMWPE (specifically, Spectra or Dyneema) and PET. Mr. Goodwin and Dr. Steckel jointly prepared the '511 application that ultimately led to the '446 patent. I understand that Dr. Steckel was Mr. Goodwin's principal contact with respect to the preparation and prosecution of the '446 patent and that materials during prosecution were sent to Mr. Hunter.

60. As discussed in paragraph 49, *supra,* the examiner rejected claims 21-24 (all claims then being examined) as being unpatentable over Burgess. Burgess contains the following disclosure:

> According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.
>
> The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost

> perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

61. In responding to this rejection, Mr. Goodwin represented to the examiner that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester, then "he would inevitably design an unacceptable suture." In his response, Mr. Goodwin also represented to the examiner that the braided combination disclosed in Burgess would have "poor knot strength properties."

62. Dr. Steckel's testimony regarding the use of UHMWPE in a braided suture is the opposite of what Mr. Goodwin represented to the examiner. Dr. Steckel also testified that he and Mr. Hunter discussed braiding UHMWPE and polyester prior to the filing date of the '511 application and that they believed it would lead to an acceptable suture. Further, Dr. Steckel testified that at the time he considered such a combination to be "a good idea" and that braiding UHMWPE and polyester together would result in "improved knot strength."

63. In my opinion, the arguments presented to the examiner with respect to alleged distinctions between the claimed invention (assuming the claims include UHMWPE) and Burgess are inconsistent with Dr. Steckel's testimony. It is also my opinion that, accepting Dr. Steckel's testimony as true, the representations made to the examiner are misrepresentations in highly material respects, because they were made for the purpose of overcoming a prior art rejection in order to obtain the allowance of claims for issuance in a patent.

EXHIBITS

64. I have not at this time prepared any exhibits which I expect to use as summary of or support for my opinions. However, I would expect to use during my testimony at trial at least some of the documents listed above under "Information Considered". I may also use demonstrative exhibits, summaries, or other exhibits that are not yet prepared, to further illustrate my testimony. I understand that such exhibits would be exchanged with opposing counsel at a time to be mutually agreed upon or required by the Court.

COMPENSATION

65. I am being compensated for my work on this case at my customary rate of $600 per hour, plus expenses. My compensation is not based on the outcome of the litigation.

March 3, 2006

John F. Witherspoon

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Expert Report of John F. Witherspoon was served, via Fedex (Saturday delivery to Ms. Malinoski and regular delivery to Mr. Gleason), along with a courtesy copy of the text of this report (without exhibits), via email, on the following counsel for Plaintiff on the 3rd day of March 2006:

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s/Salvatore P. Tamburo

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	)	Civil Action No. 04-12457 PBS

EXPERT REPORT OF JOHN F. WITHERSPOON
WITH RESPECT TO ISSUES OF INFRINGEMENT

INTRODUCTION

I am the same John F. Witherspoon who submitted an Expert Report in this litigation on March 3, 2006, with respect to issues on which the defendant Arthrex has the burden of proof, which report I incorporate herein by reference. I understand that I may also be called to present expert testimony at trial regarding issues of infringement, including willful infringement, and I have been asked to prepare a report with respect to that possible testimony.

I continue to reserve the right to file a report in rebuttal to those filed on behalf of the plaintiff, as well as the right to supplement my report(s) so as to accommodate the discovery of any additional information that may impact my testimony and opinions.

The bases for my testimony and opinions in this report are the materials identified in paragraphs 11 and 12 of my March 3 report, plus the following additional materials that I have now considered.

a) Expert Report of Martin J. O'Donnell dated March 3, 2006;

b) Expert Report of Dr. David Brookstein dated March 3, 2006;

c) Transcript of deposition testimony of Stephen A. Soffen given on January 4, 2006;

d) Transcript of deposition testimony of John Schmieding given on May 5, 2005, August 24, 2005 and January 5, 2006;

e) Transcript of 30(b)(6) Deposition of E. Richard Skula given on February 10, 2006;

f) Documents bearing Bates Nos. ARM 24283-407 and 24772-801;

g) Discussion with John Schmieding;

h) Discussion with Dr. Debi Prasad Mukherjee; and

i) Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters.

GENERAL CONSIDERATIONS

1. A claim of a patent may be infringed either literally or under the doctrine of equivalents. Literal infringement requires that an accused process, machine, manufacture or composition of matter (hereinafter collectively "product") possess every element or limitation of a given claim. The doctrine of equivalents permits a finding of infringement even where one or more limitations of a claim is not literally present in an accused product. Thus, infringement requires that each element or limitation of a claim be present either literally or equivalently in an accused product. This is sometimes called the "all elements" rule.

2. Determining infringement entails a two-step analysis—first, a claim must be construed and then the properly construed claim is compared with the accused product. With respect to the first step, a claim must be interpreted in light of its language, other claims in the patent, the specification of the patent, and the prosecution history of the patent. Interpreting a claim in light of the specification should be distinguished from reading a limitation from the specification into the claim. That is, the specification can be used to interpret the meaning of terms in a claim, but cannot be used to read a limitation into the claim. The scope of a claim is normally not limited to the specific embodiment or embodiments disclosed in the specification and drawings. The prosecution history also may affect the meaning of a term in a claim. A claim must be interpreted the same way for purposes of validity and for purposes of infringement.

3. With respect to the second step, a common practice for determining literal infringement is to carry out a "read on" test. This exercise entails reading the claim from beginning to end, but interrupting the reading after each element or limitation to ask: is this element or limitation present in the accused product? If upon completing the exercise, the answer to every question is "yes," then the claim is literally infringed. If any one answer is "no," then literal infringement does not exist.

4. If the difference between a claim element and a corresponding element of an accused product is insubstantial, then infringement under the doctrine of equivalents may exist. In practice, this may be shown in any of a number of ways. For example, the element in question in the accused product may be shown to perform substantially the same function, in substantially the same way, to obtain substantially the same result as the element of interest in the claim. Evidence of the known interchangeability of the

element of interest in the claim with the element in question in the accused product is also relevant, as is evidence of copying. It is inappropriate to apply the doctrine of equivalents in such a way as to vitiate an element or limitation in a claim.

5. Application of the doctrine of equivalents is sometimes limited by a countervailing doctrine, known as prosecution history estoppel. This doctrine, simply stated, is that a patentee cannot assert a scope of protection under the doctrine of equivalents that is inconsistent with amendments, statements or arguments made by an applicant in the PTO. The public is entitled to rely on the prosecution history in deciding whether a given product is or is not outside the coverage of the patent. Application of the doctrine of equivalents is also limited by the prior art, *i.e.,* the range of equivalents cannot be extended to cover a product that is not patentable over the prior art.

6. Amending a claim to narrow its scope for a reason relating to patentability (for example, to overcome a rejection based on prior art) may give rise to prosecution history estoppel. An applicant's decision to narrow her claims through amendment is presumed to be a general disclaimer by the applicant of all subject matter encompassed by the original claim, but not encompassed by the amended claim. A patentee can overcome this presumption only by establishing (1) that the equivalent was unforeseeable at the time the application was filed, (2) that the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question, or (3) that there is some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.

7. Another doctrine, known as the "reverse doctrine of equivalents," applies in the situation where an accused product literally contains every element or limitation set forth in

a claim, but the product functions in accordance with a different mode of operation than what is described in the patent. Under those circumstances, the accused product is deemed under the reverse doctrine of equivalents not to be an infringing product.

8. The kind of infringement discussed above is known as "direct" infringement. Infringement can also be "indirect". Indirect infringement may occur in one of two ways: (1) by actively inducing another to infringe a claim of a patent, *e.g.,* a manufacturer instructing a customer to use a product in a particular way, which, if done, would result in a direct infringement, and (2) by contributorily infringing the claim of a patent, *e.g.,* by selling a component of a patented product constituting a material part of the product, knowing the component to be especially made for use in an infringement of a claim of the patent, and which is not a staple article or commodity of commerce suitable for substantial non-infringing use. Whoever actively induces infringement is liable as an "infringer"; whoever engages in the second type of activity mentioned above is liable as a "contributory infringer."

9. The concept of "willful infringement" is based on the notion that a party found to be an infringer did so with an intentional disregard of legal rights. The determination of willfulness must take into account the totality of the circumstances, which usually includes many factors that are evaluated and weighed by the trier of fact. Infringement is recognized as resulting from activity ranging from the unknowing or accidental to the deliberate or reckless disregard of a patentee's legal rights. Willful infringement focuses on the upper portion of that range. It must be proved by clear and convincing evidence.

10. The phrase "consisting essentially of" in the transitional part of a claim closes the claim to the named elements that are recited in the claim and allows only for the

inclusion of non-recited elements or materials that do not materially affect the basic and novel characteristics of the invention. The material effect can be either beneficial or detrimental. The term "comprising" leaves a claim open to the inclusion of elements that are not expressly recited in the claim. Therefore, amending a claim by replacing the word "comprising" with the phrase "consisting essentially of" is a narrowing amendment and, when made for a reason relating to patentability, may give rise to prosecution history estoppel. The fact that an element or material is disclosed in the specification does not necessarily mean that it does not materially affect the basic and novel characteristics of the invention. The question must still be resolved as to whether in fact it materially affects the basic and novel characteristics of the invention. Thus, the discussion in paragraph 37 of Dr. Brookstein's report is based on an erroneous understanding of the law.

11. It is not unusual for an applicant not to claim all of the subject matter disclosed in the specification. Sometimes claims filed with the original application themselves do not cover all of the disclosed subject matter. Very frequently amendments made during prosecution limit a claim such that it does not cover subject matter disclosed in the specification.

12. Sometimes the body of a claim contains a so-called "Markush" expression. A Markush expression occurs most frequently in claims directed to chemical subject matter and is employed in a situation where alternative materials or ingredients (*e.g.*, ingredients A, B or C) are sought to be recited in a claim, but no generic term embracing these ingredients exists in the art. Under such circumstances, the drafter of the claim is permitted to recite language taking the form of: "a member [or similar language] selected

from the group consisting of A, B and C." This kind of language has come to be known as a "Markush" expression since it reflects a practice authorized by a 1925 decision of the Commissioner of Patents involving an application filed by an inventor named Markush. Amending a claim to ins ert a Markush expression usually amounts to a narrowing of the claim and, when this is done for a reason relating to patentability, the amendment may give rise to prosecution history estoppel.

SPECIFIC CONSIDERATIONS

Claim Construction

13. I understand that the parties disagree about whether the term "PE" in the asserted claims covers UHMWPE, and that the Court will resolve this dispute. One valid reason for the Court not to construe PE to encompass UHMWPE can be found in the prosecution history of the '446 patent. As explained in my March 3 report, in an Amendment mailed to the PTO on August 6, 1992, the applicants argued that their claimed suture was totally different from the fishing line disclosed in the Burgess prior art reference, upon which the examiner had rejected the applicants' claims, because the braided combination of UHMWPE and polyester in Burgess would be an "unacceptable suture" and have "poor knot strength properties." Because of these arguments, the public would be entitled to conclude that PE in the applicants' claims was not intended to include UHMWPE.

14. I also understand that the parties disagree as to what constitutes the basic and novel characteristics of the claimed invention, *i.e.,* the scope of the expression "consisting essentially of."

No Infringement

15. If the Court construes PE not to include UHMWPE, then no claim is literally infringed by the FiberWire, TigerWire and FiberStick products for that reason alone. Nor would any claim be infringed under the doctrine of equivalents, because the differences in properties between UHMWPE and other materials in the first fiber-forming group are substantial. My testimony in this regard would be based upon the expected testimony of Dr. Mukherjee, as set forth in his report. Moreover, the prosecution history discussed in paragraph 13, *supra*, gives rise to an estoppel by argument with respect to UHMWPE, because the applicants made this argument to successfully overcome a prior art rejection.

16. In an Amendment mailed on August 4, 1993, the applicants deleted the word "comprising" and inserted the language "consisting essentially of." The applicants also amended their claims to require that each yarn from the first set is composed of filaments of "a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE," and that each yarn from the second set is composed of filaments of "a second fiber-forming material selected from the group consisting of PET, nylon and aramid." These amendments are all narrowing amendments made to overcome rejections on prior art. Therefore, the applicants' decision to do so is presumed to be a general disclaimer of all subject matter covered by the unamended claims, but not covered by the amended claims. FiberWire, TigerWire and FiberStick are such products. The presumption is conclusive, unless the plaintiff can establish that one of the three conditions set forth in paragraph 6, *supra,* applies, and I do not presently understand that any of these conditions does apply.

17. As I explained above, the language "consisting essentially of" excludes the presence of a non-recited component which materially affects the basic and novel characteristics of the invention. I understand that the coating on FiberWire, TigerWire and FiberStick is such a component, and for this additional reason these products do not infringe. Further, I understand that the nylon in TigerWire is such a component, and constitutes yet another reason as to why this product does not infringe. Finally, I understand that the adhesive on FiberStick is such a component, and constitutes yet another reason as to why this product does not infringe. My opinions in this regard are based upon the expected testimony of Dr. Mukherjee, as set forth in his report.

18. I understand that Pearsalls only makes a braid, but not a suture as required by the claims of the '446 patent. I also understand that the braid itself is suitable for a substantial non-infringing use. Therefore, Pearsalls cannot properly be found to be a contributory infringer. My opinion in this regard is based upon the expected testimony of Dr. Mukherjee, as set forth in his report.

19. Further, if the Court construes PE to include UHMWPE, no claim is infringed by FiberWire, TigerWire or FiberStick by reason of the reverse doctrine of equivalents. I understand that these products function in a fundamentally different way than the teachings of the '446 patent. My opinion in this regard is based upon the expected testimony of Dr. Mukherjee, as set forth in his report.

No Willful Infringement

20. The extensive discussions between Mr. Soffen and representatives of Arthrex, after becoming aware of the '446 patent, clearly show that it was reasonable for Arthrex's management to continue its then ongoing FiberWire suture business, and that a

decision to do so does not amount to willful infringement. My reasons for this conclusion are set forth in the discussion below (wherein exhibit citations are to plaintiff's exhibits, unless otherwise indicated).

21. Mr. Skula, counsel for Johnson & Johnson, advised Mr. Soffen, counsel for Arthrex, of the existence of the '446 patent by telephone on December 1, 2003, and sent him a copy of the patent by letter dated that same day. Exh. 243.

22. Mr. Soffen advised John Schmieding, Arthrex's general counsel, of Mr. Skula's communication also on that day. Mr. Soffen indicated that he had not had a chance to review the patent, but that he had ordered its file history. Exh. 244. This was the beginning of a series of extensive communications, by e-mail and by telephone, between Mr. Soffen and Mr. Schmieding over the next several months. Mr. Grafton, Arthrex's then Head of Engineering and an inventor of FiberWire, was copied on many of these communications and in some instances participated in the discussions. Mr. Soffen also communicated with Mr. Skula on several occasions during this time period. Exh. 244.

23. On the very next day, Mr. Soffen sent an e-mail to Mr. Schmieding and Mr. Grafton reporting that he had undertaken an initial review of the patent that morning and went on to make a number of points that bear directly on the question of infringement. Thus, Mr. Soffen pointed out that claim 1 (the only independent claim in the patent) contained the language "consisting essentially of." He explained the legal definition of that language. He explained how this language is important in the consideration of whether the claim covers FiberWire, if FiberWire has a silicone coating,

which he understood to be the case, but which he asked Mr. Grafton to confirm. Exh. 245.

24. Later that day, Mr. Grafton sent an e-mail to Messrs. Soffen and Schmieding setting forth some of his thoughts about the '446 patent and how FiberWire is different. He also indicated that he was contacting Pearsalls in order to identify possible additional prior art. Exh. 246.

25. Two days later, on December 4, 2003, Mr. Soffen reported to Messrs. Schmieding and Grafton that his associate, Mr. McGee, had uncovered the Silvestrini patent "in the course of conducting a validity search on Ethicon Patent No. 5,314,446." A copy of Silvestrini was attached. Mr. Soffen reported that, apart from the fact that Silvestrini discloses a prosthesis, rather than a suture, the Silvestrini disclosure "meets the recited elements of claim 1" of the '446 patent. He demonstrated this in a claim chart attached to his e-mail. Mr. Soffen explained that a core is not required by claim 1. Exhs. 248 and 249.

26. On December 5, Mr. Soffen e-mailed Messrs. Schmieding and Grafton with an updated search report. He pointed out also that he needed to review the file history of the '446 patent. This was followed up by an e-mail on December 9 in which Mr. Soffen forwarded a memo prepared by Mr. McGee regarding the file history. Exh. 251.

27. On December 11, Mr. Soffen sent an e-mail to a Mr. Ellis, with a copy to Messrs. Schmieding and Grafton, thanking Mr. Ellis for the time in discussing matters involving a validity study of the '446 patent. Exh. 252.

28. On December 15, Mr. Soffen sent a letter to Mr. Skula acknowledging Mr. Skula's letter of December 1 and asked for documentation evidencing the date of

invention of the subject matter in the '446 patent in order that he might "accurately and fully evaluate" another reference, a U.S. patent to Chesterfield which has a filing date 16 days before the filing date of the '446 patent. Mr. Skula had access to such evidence. Exh. 253.

29. On December 23, Mr. Soffen reported to Messrs. Schmieding and Grafton that he had spoken to Mr. Skula that day to remind him that he was awaiting a response with respect to Chesterfield. He also reported to the client justification for "a strong position on non-infringement by relying upon the inclusion of a coating in FiberWire." In doing so, Mr. Soffen called attention to the fact that the claims of the '446 patent recite "consisting essentially of." In the e-mail Mr. Soffen also explained his understanding of what the '446 patent had to say about coatings. Exh. 254.

30. On January 5, 2004, Mr. Grafton responded by saying that he understood Mr. Soffen's "logic" and that it "sounds like a good additional avenue to pursue." A copy of the e-mail was sent to Mr. Schmieding. Exh. 255.

31. On January 9, Mr. Soffen wrote Mr. Skula to explain that he had now reviewed the file history and that, apart from the validity issue raised in his earlier letter of December 15 relating to the Chesterfield patent, he had determined that FiberWire does not infringe "because, among other reasons, it includes a coating (specifically a silicone coating)." Mr. Soffen elaborated on his thinking in this regard. Exh. 256.

32. On January 13, Mr. Soffen sent an e-mail to Messrs. Schmieding and Grafton. Exh. 260. It reads as follows:

> I spoke with Don G. this afternoon. Don is going to get samples of FiberWire from Pearsalls with and without the silicone coating, so that we can demonstrate that the coating affects the "basic and novel properties" (friction/pliability) of the suture.

33. By letter dated January 16, Mr. Skula told Mr. Soffen that Ethicon continues to assert infringement, notwithstanding the arguments presented in Mr. Soffen's letter of January 9. Mr. Skula explained that he also disagreed with Mr. Soffen's reading of the '446 patent. In addition, Mr. Skula said that "Ethicon has written documentation, which I have reviewed, that establishes a date of invention prior to the February 2, 1992 filing date of the Chesterfield patent." Finally, Mr. Skula stated, without explanation, that he believed that the disclosure of Chesterfield does not render the '446 patent invalid. Exh. 261.

34. On January 20, Mr. Soffen sent an e-mail to Mr. Schmieding, with copies to Messrs. Grafton, Price, and R. Schmieding, in which he forwarded a copy of Mr. Skula's January 16 letter. Mr. Soffen made two points. First, that although "obviously not reflected in his letter, Rich acknowledged orally to me that he understood Arthrex's position, and that the parties had a legitimate dispute (*i.e.,* he doesn't consider our position totally meritless)." Second, Mr. Soffen explained that

> The statement in Rich's letter that the disclosure of the Chesterfield patent, if prior art, does not render the Ethicon patent invalid is curious (perhaps overreaching), since the FiberWire structure is very close to the structure disclosed in the Chesterfield patent (although it does not infringe the claims, for reasons stated previously).

Mr. Soffen concluded the e-mail by saying that "We can discuss this at our meeting tomorrow afternoon." Later that day, Mr. Schmieding sent a return e-mail to Mr. Soffen to advise him that he had some coated and non-coated samples and that he would hold them until a decision is reached about testing. Mr. Schmieding called Mr. Soffen's attention to the fact that the DFU for FiberWire says "the coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue." Exh. 262.

35. On January 22, Mr. Soffen sent an e-mail to Mr. Schmieding, with a copy to Messrs. Grafton, Price and R. Schmieding. ARM 24328. The first paragraph reads:

> When I spoke with Rich this evening, he asked me where Arthrex stood on the FiberWire infringement issue. I responded that Arthrex was arranging for tests to be conducted to quantify the effect of the coating on the "basic and novel properties" of the FiberWire suture, and that we expected to be able to get back to him in about three weeks. He accepted this as a valid course of action, and told me that he would report it to Ethicon.

36. On January 27, Mr. John Schmieding sent an e-mail to Mr. Soffen with some patents that he had found. He briefly discussed each patent. The e-mail was forwarded to Mr. McGee, and on January 29 Mr. McGee sent an e-mail to Mr. Soffen commenting on the patents. Mr. McGee's comments were forwarded to Mr. Schmieding. Exh. 263.

37. On February 3, Mr. Soffen sent an e-mail to Messrs. Schmieding and Grafton informing them that Mr. Skula "called today" for an update as to when Arthrex expects to receive the results of the FiberWire coating test. He went on to say:

> On the one hand, Rich states that Ethicon is anxious for the test results, and on the other hand, Rich states that Ethicon is convinced that the coating is meaningless since FiberWire has a heterogenous braid which serves the purpose and function stated in the patent. Rich emphasized that Ethicon is putting considerable pressure on him to push the matter along.

Mr. Grafton replied that he did not expect the results to be completed until late the next week, and Mr. Soffen said that would be fine. Also, Mr. Soffen asked Mr. Grafton that he be advised as to how the test is to be conducted in order that he could confirm that it would serve the purpose with respect to comparing the FiberWire coating to the claims of the '446 patent. Exh. 265.

38. On February 3, Mr. Soffen sent an e-mail to Mr. Schmieding, with a copy to Mr. McGee, in which Mr. Soffen explained the pertinence of the disclosure of the

Silvestrini reference, and indicated that he would order a copy of the thesis mentioned on the first page of the patent. Exh. 268.

39. On February 4, Mr. Soffen advised Mr. Skula, in response to Mr. Skula's status inquiry the day before, that he had been told that Arthrex expects that the FiberWire testing will be completed by the end of the following week. ARM 24295. The e-mail also said:

> As discussed, the tests are designed to determine whether the coating on FiberWire suture affects the "basic and novel properties" of the suture as claimed in the Ethicon patent at issue. We believe that, under the relevant case law, test results showing that the coating affects these properties would be highly significant, indeed determinative, with respect to the issue of infringement in light of the "consisting essentially of" language which was inserted in the claims of the Ethicon patent during prosecution.

40. On February 11, Mr. Grafton sent an e-mail to Mr. Soffen saying that "we are seeing a significant difference in our testing of coated versus non-coated FiberWire coefficient of friction. We had to tweak our test but it looks very good. We should have the report ready to send you by Friday." ARM 24294.

41. On February 13, Mr. Soffen e-mailed Mr. Skula to tell him that the test on the FiberWire product had been completed and that "the results as to the effect of the coating" are compelling. He also said that Arthrex will be sending him a report the following week, together with samples of the coated and uncoated suture. Further, Mr. Soffen advised Mr. Skula that samples of the suture had been sent for testing by a surgeon in a surgical environment. Exh. 269.

42. On February 20, Mr. Soffen wrote Mr. Skula enclosing a copy of the protocol and the results of the test conducted by Arthrex. He enclosed samples of the suture, both coated and uncoated, that were tested. He explained the test results and how those results

relate to the significance of the language "consisting essentially of" in the claims of the '446 patent. He also discussed the specification of the '446 patent and why "the braided strands of the Arthrex suture act in a reverse manner to the functions described in the specification..." Finally, Mr. Soffen reminded Mr. Skula that the braid in the FiberWire suture is similar to that described in Chesterfield and that even if Ethicon has evidence establishing a date of invention prior to the filing date of Chesterfield, which had not yet been provided, "there remains an issue of validity under 35 U.S.C. 102(g)." Mr. Soffen went on to say: "Based upon U.S. Surgical's earlier filing date, we assume that U.S. Surgical has an earlier date of invention, absent evidence to the contrary (and Ethicon has provided none)." Exh. 267.

43. On February 23, Mr. Soffen forwarded a copy of his February 20 letter to Mr. Skula to Messrs. Schmieding and Grafton. ARM 24286.

44. On March 4, Mr. Skula faxed Mr. Soffen a letter indicating that he had received the test results and arguments and that, although "your position is made clear, Mitek has not changed its position that the Arthrex FiberWire product is covered by the claims of the Hunter *et al.* patent." ARM 24285. Mr. Soffen then sent an e-mail to Messrs. Schmieding and Grafton with a copy of Mr. Skula's letter. ARM 24284.

45. In order to fully understand the significance and context of the communications described above, it is important to recognize several additional facts. Arthrex had received and relied on legal advice of Mr. Soffen on patent matters for many years. The advice was sometimes favorable and sometimes unfavorable to Arthrex's interests. Mr. Soffen visited the Arthrex facility and met with Arthrex's management frequently. He talked with Mr. Schmieding almost daily. Historically, much of the legal

advice that Arthrex receives from Mr. Soffen and relies on in the conduct of its affairs is not communicated in written form. Therefore, it is not surprising that oral communications and a series of e-mails formed the basis of Mr. Soffen's advice and were relied on by Arthrex in this matter.

46. Summarizing, upon learning of the '446 patent, Arthrex and its outside patent counsel of many years, Mr. Soffen, undertook an in depth investigation as to whether the patent was valid and infringed. The investigation began promptly. Mr. Soffen reviewed the patent and reported his initial thoughts to Arthrex within a matter of hours. He immediately ordered the file history. He immediately undertook a search of the prior art. He uncovered a very close reference, the Silvetrini reference, and laid out a claim chart for the client demonstrating its pertinence. The chart showed that all of the elements of claim 1 were disclosed except for a suture. The reference disclosed a prosthesis. Mr. Soffen uncovered another very good reference, the Chesterfield reference, but cautioned Arthrex that Chesterfield might be subject to being antedated. Mr. Soffen recognized the pertinent statutory basis upon which Chesterfield could qualify as prior art, *viz.*, 102(e) and 102(g). Mr. Soffen sought to ascertain facts as to a possible antedation by contacting Mr. Skula, who had access to those facts. Mr. Skula was not forthcoming, other than to say that he had reviewed evidence establishing that Chesterfield could be antedated.* No evidence was provided Mr. Soffen, however, either at that time or at any time prior to bringing this litigation, even though Mr. Soffen offered to hold the information in confidence. Mr. Soffen studied the prosecution history and explained to Arthrex the significance of certain amendments with respect to non-

* If Mr. Skula had in mind the evidence that I reviewed in the preparation of my March 3 report, he had an insufficient basis for making this representation.

infringement. Mr. Soffen recognized the importance of the language "consisting essentially of" in the claims, and explained its meaning to Arthrex. Arthrex conducted tests to demonstrate that the coating affects the basic and novel properties of its FiberWire suture. The test results and protocol were sent to Mr. Skula. Mr. Skula said they were unpersuasive. All of this activity took place as part of an ongoing process entailing numerous discussions and reports, by telephone and by e-mail, between Mr. Soffen, Mr. Schmieding and/or Mr. Grafton over a period of several months. T he dialogue involved matters relating to both validity and infringement. The investigation was directed by an experienced, outside patent counsel It was prompt. It was thorough. It was legally sound. It resulted in three separate grounds upon which Arthrex had good reason to believe that it was not infringing a valid patent. The evidence, viewed as a whole, demonstrates the antithesis of willfulness.

47. Mr. O'Donnell's report neither recognizes nor discusses the vast majority of the evidence discussed in paragraphs 20-45, *supra*. It is an incomplete analysis. It fails to consider the totality of the circumstances, as required by law, and arrives at a wrong conclusion.

EXHIBITS

48. I have not at this time prepared any exhibits which I expect to use as summary of or support for my opinions. However, I would expect to use during my testimony at trial at least some of the documents listed above. I may also use demonstrative exhibits, summaries, or other exhibits that are not yet prepared, to further

illustrate my testimony. I understand that such exhibits would be exchanged with opposing counsel at a time to be mutually agreed upon or required by the Court.

COMPENSATION

49. I am being compensated for my work on this case at my customary rate of $600 per hour, plus expenses. My compensation is not based on the outcome of the litigation.

March 24, 2006

John F. Witherspoon

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Expert Report of John F. Witherspoon With Respect to Issues of Infringement was served, via Fedex (Saturday delivery to Ms. Malinoski and regular delivery to Mr. Gleason), along with a courtesy copy of the text of this report (without exhibits), via email, on the following counsel for Plaintiff on the 24th day of March 2006:

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EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	Civil Action No. 04-12457 PBS

REBUTTAL EXPERT REPORT OF JOHN F. WITHERSPOON

I am the same John F. Witherspoon who submitted expert reports in this litigation on March 3, 2006 and March 24, 2006, which reports I incorporate herein by reference. I have reviewed the expert report of Dr. Matthew Hermes and I submit this report in response to aspects of Dr. Hermes' report that relate to patent practices and procedures, including his reply to certain opinions set forth in my March 3 report. I have also reviewed the Rebuttal Expert Report of Dr. Debi Prasad Mukherjee, as well as the transcript of the deposition of Donald Grafton given on March 14, 2006.

I.

1. I do not fully understand the significance of the attempt to distinguish between "a person of ordinary skill in the art" and "a person of skill in the art" in paragraph 31 of the Hermes report, because this seems to suggest that the level of skill of the persons referenced in sections 103 and 112 of the statute is not the same. I am not aware of any authority in support of this position.

2. Much of the discussion in the sections of the Hermes report dealing with a motivation to combine various prior art references is based on a number of false premises. (See, especially paragraphs 48-60, 110-117, 125-129 and 139-142.) For example, the report suggests that the motivation must be found in the references themselves. That is not a requirement. The teaching, motivation, or suggestion to combine relevant prior art disclosures does not have to be found explicitly in the prior art. Rather, it may be provided by a consideration of the prior art as a whole. The test is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. In this regard, the problem to be examined is not the specific problem solved by the invention, but the general problem that confronted the inventor before the invention was made, and to the extent paragraphs 21 and 22 of the Hermes report indicate otherwise, I disagree.

II.

3. In paragraphs 168-184, Dr. Hermes attempts to explain that the claimed invention was reduced to practice at least as early as February 1989. Evidence of a reduction to practice must reflect every limitation recited in the claims. I fail to find any discussion in Dr. Hermes's report of evidence demonstrating the actual making and evaluation of a sterilized surgical suture by the inventors. Further, a three year wait before filing a patent application after an alleged reduction to practice is itself some evidence that a reduction to practice may not have occurred as early as alleged.

4. The most that Dr. Hermes has identified by way of an alleged reduction to practice is a braided structure made of PTFE and PET. Even assuming that such a braid

constitutes a reduction to practice for that combination, it fails to antedate Chesterfield as a prior art reference unless it is established that that work would be understood by a person of ordinary skill in the art to have generic applicability to the claimed braided structures of sufficient scope as to embrace a braid made of UHMWPE and PET or nylon. I find no such demonstration in the Hermes report.

III.

5. In paragraphs 185-194, Dr. Hermes attempts to explain that certain statements to the examiner by the applicants' attorney, Mr. Goodwin, while prosecuting the '446 patent were not inconsistent with Dr. Steckel's testimony. I disagree with Dr. Hermes. Nothing in his report causes me to change my opinion.

6. In his deposition, Dr. Steckel gave the following testimony (page 188, line 13 to page 192, line 9):

Q. And when you say, "Spectra," if I were to substitute Dyneema, Spectra or Dyneema –
A. Yes. Yeah.
Q. – that would be a fair thing?
A. Yes.
Q. Did you have an idea of which yarn you—to braid Dyneema with?
A. Which yarn would we have braided it with?
Q. Yes, sir. Did you have that idea?
MR. BONELLA: Objection. Asked and answered.
A. Generically, one which would improve the knot strength of Dyneema.
Q. Would that include PET?
A. It would include, essentially, all of the current—all of Ethicon's non-absorbable multifilaments at the time, which would include PET, nylon, silk—that's it.
Q. So, if I understand your testimony—
A. Yes.
Q. --you had, at least in your mind—
A. Yes.
Q. --the idea of braiding together Dyneema and PET.
A. It was one of the combinations, yes.
Q. And did you have a view—and when did you have this idea?

A. This—this would date back to the early conversation with Al Hunter in terms of what benefits could we derive from forming composites of dissimilar fibers.
Q. Did you have—in formulating this idea, did you have any sort of belief that if you put Dyneema together with PET, it would lead to an acceptable suture?
A. It would lead to a suture with potentially improved properties over Ethibond.
Q. Did you have a belief as to whether that would be an acceptable suture?
MR. BONELLA: Objection. Asked and answered.
A. We had a belief that it could lead to—as you're saying—an acceptable suture. There were other issues that we didn't know. For example, how the—how polyethylene behaved in the body. So, it was a high priority. Polyethylene, even though there was an interest, it wasn't a—it wasn't something that was a high priority at the time.
Q. The thought didn't cross your mind that, Oh, this would make an unacceptable suture to put Dyneema together with PET?
A. My recollection was—an unacceptable suture or an acceptable?
Q. An unacceptable suture.
A. Well, the concern with any of the very high-strength fibers was always knot strength, and that was true whether it was Dyneema, Spectra, Kevlar, etcetera. So, the general view was, I mean, all of those—100 percent, all of those, Ethicon evaluated at one point as a suture material. They're the world's biggest suture material company. And all of them there was an interest in how do you improve the knot strength of them, and can you—that was—that was something we discussed.
Q. I'm not sure I understand your answer.
A. Go ahead.
Q. And I'm trying to—
A. Sure.
Q. When you had this idea that you could blend Dyneema together with PET, were you—did you believe it would make an acceptable suture or an unacceptable suture?
A. No. We believed—we believed that that could offer a suture with straight tensile that was better than Ethibond, and you know, could potentially solve the knot issues, and again, that was a generic view for all of the high-tenacity fibers.
Q. You thought it was a good idea—
A. Yes. Yes.
Q. --rather than a bad idea?
A. No., we viewed—we viewed that as a potential good idea.
Q. And you didn't think, Oh, that's a bad idea.
MR. BONELLA: Objection. Asked and answered.
A. I don't know if it was good or bad. You now, it was—

Q. You thought it was a good idea?
A. We thought we could have improved knot strength, and we could get the beneficial properties of both in a blend. That's what we thought.

Thus, according to Dr. Steckel, before filing their application in the PTO the applicants believed that a braided structure of Dyneema and PET (a polyester) could have good knot characteristics. They believed that this combination could lead to an acceptable suture.

7. During prosecution of their application, however, when faced with a rejection based on a prior art disclosure (Burgess) of a fishing line having a braided structure of a high molecular weight polyethylene, Dyneema being specifically named, with polyester and/or nylon, the applicants tried to convince the examiner that their braid was patentable over the braid of the fishing line by making the following representations (Amendment mailed August 4, 1982) (all emphases in original):

> In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below: (Page 2)
>
> Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security. (Page 3)
>
> Even if he did use the teachings of the fishing line art to modify a suture, then he would inevitably design an unacceptable suture. (Pages 3-4)

The examiner's rejection on Burgess was then dropped, which the applicants acknowledged with gratitude.

8. In my opinion, the statements made to the examiner are not consistent with Dr. Steckel's testimony. On the one hand, according to Dr. Steckel, he and Mr. Hunter believed that a braid of Dyneema and PET could provide an acceptable suture with improved knot strength characteristics; on the other hand, they told the examiner that the

Burgess braid would have poor knot strength properties. It is also my opinion that the statements made to the examiner are affirmative misrepresentations, if the applicants believed that their claims included braids of Dyneema and PET. And they are highly material misrepresentations, because they were made in an attempt to overcome a rejection based on a very close prior art reference, which attempt turned out to be successful.

9. Dr. Hermes has four responses to my opinion. First, he says that in my earlier report I failed to include the words "the teachings of the fishing line art" in the last of the three quotations set forth above. I do not understand his point. My earlier discussion was clearly referring to the fishing line art as disclosed in Burgess, namely a fishing line of a braid having Dyneema filaments and filaments of polyester and/or nylon. In any event, I have now included the words in the quotation above, and my opinion remains the same. Second, Dr. Hermes says he is not clear what statements by Dr. Steckel I have in mind. The statements are easily found in the transcript and they are set forth above. Third, Dr. Hermes says that Dr. Steckel's testimony is not inconsistent with the attorney's statements. As already indicated, I very much disagree. Dr. Steckel testified that he and Mr. Hunter believed that the combination of Dyneema and a polyester could lead to an acceptable suture with improved knot strength. Mr. Goodwin represented the opposite in the applicants' successful attempt to overcome prior art. A braid that could lead to an acceptable suture with improved knot strength does not become otherwise by calling it a fishing line. Fourth, Dr. Hermes says that nothing was withheld from the examiner because the application of the '446 patent "discloses ultra high molecular weight polyethylene, UHMWPE." Dr. Mukherjee does not agree. In any

event, I fail to find any mention of the terms "Dyneema," "Spectra," "ultra high molecular weight polyethylene," or "UHMWPE" anywhere in the '446 patent. (Nor, incidentally, do I find any of this terminology anywhere in Dr. Steckel's notebooks that I reviewed.) In my opinion, no reasonable examiner would have dropped a rejection based on Burgess if she believed that the applicants' claims included a braid of Dyneema and PET, based on the arguments made by the applicants. Many of the attorney's arguments would have been irrelevant, since the claims do not recite such properties as elongation and knot strength and security, upon which to distinguish the disclosure of Burgess. In my opinion, the examiner here must have believed that the claims did not include braids of Dyneema and PET.

April 13, 2006

John F. Witherspoon

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Rebuttal Expert Report of John F. Witherspoon was served, via Fedex, on the following counsel for Plaintiff on the 13th day of April 2006:

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/s/Salvatore P. Tamburo

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts Corporation,

Plaintiff,

v.

ARTHREX, INC., a Delaware Corporation,

PEARSALLS LTD., a Private Limited Company of the United Kingdom,

Defendants.

Civil Action

No. 04-12457 PBS

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VIDEO DEPOSITION OF JOHN WITHERSPOON

Washington, D.C.

Tuesday, June 20, 2006

The videotaped deposition of JOHN WITHERSPOON was convened on Tuesday, June 20, 2006, commencing at 9:03 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, D.C., before Cynthia R. Simmons Ott, Registered Merit Reporter, Certified Realtime Reporter, and Notary Public.

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all during your first telephone conversation with Dr. Mukherjee?
MR. SABER: Objection, vague, overbroad.
THE WITNESS: Discuss it at all. I don't recall. I mean, we may have, but I don't have a specific recollection about any in depth discussion certainly.
BY MS. ELDERKIN:
Q. Do you recall if you discussed the meaning of the claims in the Hunter patent during your discussion with Dr. Mukherjee?
A. No.
Q. You don't recall?
A. I don't recall that we went into any kind of an in depth discussion of the meeting to the claims. Now, it may be also that I asked, in addition to the sterilization matter, I may have asked him some questions about the ultra high molecular weight PE. And so to that extent, I guess we at least indirectly talked about the claims.
Q. You say you may have discussed that, but you don't have any recollection now?
A. That's correct.

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Q. That you did so. Did you discuss any prior art with Dr. Mukherjee during this phone conversation?
A. I don't believe we did.
Q. Have you reviewed any prior art in connection with the opinions you've rendered?
A. Well, again, I reviewed everything that I said I reviewed that I identified in my report. All the materials identified in my report are quite lengthy, and I don't want to suggest that I reviewed everything to the same degree of depth.
Q. Do you intend to offer any opinions on the disclosures of prior art references?
MR. SABER: Objection, vague, overbroad.
THE WITNESS: Could you tell me a little more about what you mean by any opinions regarding.
BY MS. ELDERKIN:
Q. Do you plan to testify about what any prior art reference discloses?
MR. SABER: Objection vague and overbroad.
THE WITNESS: I do not intend to

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testify as a technical expert, and therefore, don't intend to testify about the contents of technical documents.
I may testify about what happened in the Patent Office in the course of the prosecution of the patent in suit, and that may entail some testimony about the contents of the prior art reference that was involved in the prosecution.
But any testimony that I would give with respect to the contents of any technical document in this case would be from the perspective of a patent lawyer and not as a technical expert, or as a person of ordinary skill in the art. To the extent I need that information to render an opinion, I would expect to rely on the expected testimony of -- or at trial, the actual testimony of Dr. Mukherjee.
BY MS. ELDERKIN:
Q. So you are not a person of skill in the art to which the patent in suit pertains?
A. Correct, I am not.
Q. Did you talk about the prosecution history for the Hunter patent during this first

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phone conversation with Dr. Mukherjee?
A. I don't recall that we did. Well, again, I guess your question is rather broad. Specifically this prosecution history, I don't recall that we did. And I guess that was your question.
Q. Right. Did Dr. Mukherjee ask you any questions during this phone conversation?
MR. SABER: Objection, asked and answered.
THE WITNESS: I'm sure he did.
BY MS. ELDERKIN:
Q. Do you recall any?
A. No.
Q. I'm sorry, that was no?
A. No.
MR. SABER: Objection, asked and answered.
BY MS. ELDERKIN:
Q. Do you recall what period of time before you signed your first expert report you had this phone conversation with Dr. Mukherjee?
A. A matter of a few days.
Q. Did you see Dr. Mukherjee's first expert report before you executed your first

EXHIBIT 5

LEXSEE 2006 US DIST LEXIS 54260

Analysis
As of: Jul 11, 2007

THE PROCTOR & GAMBLE COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.

Civil Action No. 04-940-JJF

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2006 U.S. Dist. LEXIS 54260

August 4, 2006, Decided

SUBSEQUENT HISTORY: Motion granted by *P&G v. Teva Pharms. USA, Inc., 2006 U.S. Dist. LEXIS 54300 (D. Del., Aug. 4, 2006)*

CASE SUMMARY:

PROCEDURAL POSTURE: In a patent infringement action, defendant filed a motion to preclude the testimony of plaintiff's patent law expert.

OVERVIEW: The court held that pursuant to *Fed. R. Evid. 702*, *704*, testimony by the expert had to be restricted to U.S. Patent and Trademark Office practice and procedures and could not include legal conclusions or substantive issues of patent law. In response to defendant's motion, plaintiff's expert removed his legal opinions on two-way testing in the amended rebuttal expert report. Plaintiff agreed to refrain from soliciting the expert's opinion about which test for obviousness-type double-patenting should apply in this case. Despite plaintiff's assurances, the court concluded that the section of the expert's report containing such opinions had to be stricken because it contained inadmissible legal conclusions.

OUTCOME: The court granted defendant's motion and struck the disputed testimony from the expert's amended rebuttal report.

LexisNexis(R) Headnotes

Evidence > Procedural Considerations > Preliminary Questions > Admissibility of Evidence > General Overview
[HN1] A court has broad discretion to admit or exclude evidence under the Federal Rules of Evidence.

Evidence > Procedural Considerations > Preliminary Questions > Admissibility of Evidence > General Overview
Evidence > Testimony > Experts > Admissibility
[HN2] See *Fed. R. Evid. 702*.

Evidence > Testimony > Experts > Ultimate Issue
[HN3] The Federal Rules of Evidence do not permit expert testimony as to legal conclusions. *Fed. R. Evid. 704*.

Evidence > Testimony > Experts > Ultimate Issue
Patent Law > Infringement Actions > General Overview
[HN4] The court excludes testimony by patent law experts on substantive issues of patent law.

COUNSEL: [*1] For The Procter & Gamble Company, Plaintiff: Frederick L. Cottrell, III, Steven J. Fineman, Richards, Layton & Finger, Wilmington, DE.

For Teva Pharmaceuticals U.S.A., Inc., Defendant: Adam Wyatt Poff, Josy W. Ingersoll, Young, Conaway, Stargatt & Taylor, Wilmington, DE.

JUDGES: Joseph J. Farnan Jr., UNITED STATES DISTRICT JUDGE.

OPINION BY: Joseph J. Farnan Jr.

OPINION

MEMORANDUM ORDER

Pending before the Court is Defendant Teva Pharmaceuticals USA, Inc.'s Motion To Preclude The Testimony Of Plaintiff's Patent Law Expert (D.I. 69). For the reasons discussed, the Motion will be granted in part and denied in part.

I. BACKGROUND

In this patent infringement case, Defendant argues that Plaintiff's patent, U.S. Patent No. 5,583,122 ("the '122 patent") is invalid because of obviousness-type double patenting. Plaintiff submitted the Rebuttal Expert Report of Jerry D. Voight in response to Defendant's Expert Report of George R. Lenz, Ph.D., to address patent interference practices and whether the one-way or two-way test should be used for determining obviousness-type double patenting in this case. (D.I. 70 Ex. A). On July 6, 2006, Defendant filed the instant Motion to preclude [*2] Plaintiff from proffering Mr. Voight's testimony on any of the opinions set forth in his expert report. (D.I. 69). Defendant contends that Mr. Voight's testimony would exceed the scope permitted by the Court because it will include legal conclusions and goes beyond the practices and procedures of the U.S. Patent and Trademark Office (PTO). (D.I. 69 at 3). In Response, Plaintiff contends that Mr. Voight's expert testimony is within the parameters permitted by the Court because it includes the workings of the PTO and the prosecution history in this case. (D.I. 74). Plaintiff's answering brief included an Amended Rebuttal Expert Report of Jerry D. Voight, removing certain legal conclusions, and now contends that Defendant's concerns are moot. [1] (D.I. 74 Ex. A).

1 For the purposes of its review of this Motion, the Court considers only the Amended Rebuttal Expert Report of Jerry D. Voight (D.I. 74 Ex. A).

II. DISCUSSION

[HN] A court has broad discretion to admit or exclude evidence under the *Federal Rules* [*3] *of Evidence. Gumbs v. Int'l Harvester, Inc., 718 F.2d 88, 97 (3d Cir. 1983). Federal Rule of Evidence 702* states that

> [HN] If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. [HN] The Rules of Evidence do not permit expert testimony as to legal conclusions. *Salas by Salas v. Wang, 846 F.2d 897, 905 n.5 (3d Cir. 1988)*; *see Fed. R. Evid. 704*.

[HN] This Court excludes testimony by patent law experts on substantive issues of patent law. (D.I. 70 Ex. C, D); *Revlon Consumer Prods. Corp. v. L'Oreal S.A., 1997 U.S. Dist. LEXIS 4117, at *9-10 (D. Del. March 26, 1997)*. Testimony by Mr. [*4] Voight must therefore be restricted to PTO practice and procedures and may not include legal conclusions or substantive issues of patent law.

In response to Defendant's Motion, Plaintiff's expert removed his legal opinions on two-way testing in the Amended Rebuttal Expert Report. (D.I. 74 Ex. A). Plaintiff agrees to refrain from soliciting Mr. Voight's opinion about which test for obviousness-type double-patenting should apply in this case. (D.I. 74 at 7). Despite Plaintiff's assurances, the Court concludes that section "V. Opinions and Basis Therefor," subsection "A. Legal Background for Opinions" of Mr. Voight's report must be stricken because it contains inadmissible legal conclusions. (D.I. 74, Ex. A at 10-11).

ORDER

NOW THEREFORE IT IS HEREBY ORDERED that Defendant Teva Pharmaceuticals USA, Inc.'s Motion To Preclude The Testimony Of Plaintiff's Patent Law Expert (D.I. 69) is ***GRANTED*** and section V., subsection A., of Mr. Voight's "Amended Rebuttal Expert Report" (D.I. 74 Ex. A at 10-11), is stricken.

August 4, 2006

Joseph J. Farnan Jr.

UNITED STATES DISTRICT JUDGE

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EXHIBIT 6

LEXSEE 2006 U.S. DIST. LEXIS 77966

Positive
As of: Jul 11, 2007

PFIZER INC., PHARMACIA CORP., PHARMACIA & UPJOHN INC., PHARMACIA & UPJOHN COMPANY, G.D. SEARLE & CO, G.D. SEARLE LLC, SEARLE LLC (DELAWARE) and SEARLE LLC (NEVADA), Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.

CIV. ACTION NO. 04-754 (JCL)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

2006 U.S. Dist. LEXIS 77966

October 26, 2006, Decided

SUBSEQUENT HISTORY: Motion denied by *Pfizer Inc. v. Teva Pharms. USA, Inc., 2006 U.S. Dist. LEXIS 77967 (D.N.J., Oct. 26, 2006)*

PRIOR HISTORY: *Pfizer Inc. v. Teva Pharms. USA, Inc., 2006 U.S. Dist. LEXIS 74849 (D.N.J., Oct. 13, 2006)*

CASE SUMMARY:

PROCEDURAL POSTURE: In this patent infringement action, before the court was plaintiffs' motion in limine to preclude the trial testimony of defendant's proposed patent law expert.

OVERVIEW: The expert was a registered patent attorney with nearly forty years of experience in the field of patent law. According to his reports, the expert intended to offer testimony on a wide range of issues. The court found that expert testimony that extended beyond factual presentation and approximates legal argument would not help the court. Accordingly, the court precluded the expert's testimony explicating the law generally or offering legal conclusions that follow from the facts presented at trial. The expert may not testify regarding his opinion that plaintiffs' limited disclosure during prosecution of the patents-in-suit violated the best mode requirement, his opinion that plaintiffs violated their duty of disclosure and the restriction requirement, or his opinion that a certain patent was material to patentability and not cumulative to the other references considered during the examination of the patents-in-suit. The court also found that the expert would be permitted to testify as to Patent and Trademark Office practice and procedure and factual information regarding the prosecution history of the applications that issued as the patents-in-suit.

OUTCOME: The court precluded the expert's testimony to the extent he planned to testify as to general principles of patent law or to offer legal opinions.

LexisNexis(R) Headnotes

Evidence > Testimony > Experts > Admissibility
Evidence > Testimony > Experts > Helpfulness
[HN1] See *Fed. R. Evid. 702*.

Evidence > Testimony > Experts > Ultimate Issue
[HN2] In civil cases, *Fed. R. Evid. 704* expressly permits expert opinion testimony that embraces an ultimate issue to be decided by the trier of fact. However, *Rule 704* was not intended to allow experts to offer opinions embodying legal conclusions. Indeed, the United States Court of Appeals for the Third Circuit has explicitly held that it is not permissible for a witness to testify as to the governing law, or as to legal conclusions.

Evidence > Testimony > Experts > Ultimate Issue

[HN3] Expert testimony that extends beyond factual presentation and approximates legal argument will not help the court, but will indeed hinder it as non-evidential testimony prolongs what is already anticipated to be a lengthy bench trial.

COUNSEL: [*1] For PFIZER INC., PHARMACIA CORP., PHARMACIA & UPJOHN INC., PHARMACIA & UPJOHN COMPANY, G.D. SEARLE & CO., SEARLE LLC(DELAWARE), SEARLE LLC(NEVADA), G.D. SEARLE LLC, Plaintiffs: DAVID E. DELORENZI, SHEILA F. MCSHANE, GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE, PC, NEWARK, NJ.

For TEVA PHARMACEUTICALS USA, INC., Defendant: MICHAEL E. PATUNAS, LITE DEPALMA GREENBERG & RIVAS, LLC, NEWARK, NJ.

JUDGES: John C. Lifland, U.S.D.J.

OPINION BY: John C. Lifland

OPINION

Pfizer's Motion In Limine No. 1

LIFLAND, District Judge

This case arises out of Teva Pharmaceuticals U.S.A., Inc.'s ("Teva" or "Defendant") alleged infringement of *U.S. Patent Nos. 5,466,823*; *5,563,165*; and *5,760,068* (the "patents-in-suit"), which are held by Pfizer, Inc., Pharmacia Corp., Pharmacia & Upjohn Inc., Pharmacia & Upjohn Company, G.D. Searle & Co., G.D. Searle LLC, Searle LLC (Delaware), and Searle LLC (Nevada) (collectively "Pfizer" or "Plaintiffs"). The patents-in-suit are directed toward celecoxib, the active ingredient in Celebrex, and a broad genus of compounds that includes celecoxib, pharmaceutical compositions including such compounds, and methods of using such compounds.

Before the Court is Pfizer's [*2] motion in limine No. 1 to preclude the trial testimony of Teva's proposed patent law expert, Ronald H. Smith. For the reasons explained herein, the Court will preclude Mr. Smith's testimony to the extent he plans to testify as to general principles of patent law or to offer legal opinions.

Mr. Smith is a registered patent attorney with nearly forty years of experience in the field of patent law. He was employed as an examiner at the Patent and Trademark Office ("PTO") for 33 years, and later joined a law firm where he worked as a patent attorney prosecuting patent applications at the PTO on behalf of inventors. Mr. Smith's credentials are not in question. According to his reports, Mr. Smith intends to offer testimony on a wide range of issues, including: PTO Practice and Procedure; the prosecution history of the applications that issued as the patents-in-suit; his opinion that Pfizer's limited disclosure during prosecution of the patents-in-suit violates the best mode requirement; his opinion that Pfizer violated its duty of disclosure and the restriction requirement; the use of objective indicia of obviousness at the PTO; PTO criteria for determining the weight and sufficiency of [*3] evidence purporting to demonstrate unexpected results in chemical cases; his opinion that Pfizer's expert's comparison of Celebrex and SC-58125 does not demonstrate unexpected results; his opinion that Pfizer's expert's comparison of Celebrex and Vioxx does not demonstrate unexpected results; and finally, his opinion that the Merck *U.S. patent No. 5,474,995* ("Merck *'995 patent*") is not cumulative to the other references considered during the examination of the patents-in-suit, and would be material to patentability. (Declaration of Daniel L. Reisner in Support of Pfizer's Memorandum of Law in Support of its Motion in Limine No. 1 (hereinafter, "Reisner Decl."), Ex. A, at 5; Reisner Decl., Ex. B, at 2; Reisner Decl., Ex. C, at 2.)

Teva contends that Mr. Smith's proposed testimony may assist the trier of fact, and is therefore admissible under *Federal Rule of Evidence 702*, which states:

> [HN] If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in [*4] the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

To the extent that Pfizer argues that the Court should exclude the testimony because it is improper for an expert witness to explain the law to the fact-finder or to offer opinions about legal conclusions, the Court agrees.

[HN] In civil cases, *Rule 704* expressly permits expert opinion testimony that "embraces an ultimate issue to be decided by the trier of fact." However, "*Rule 704* was not intended to allow experts to offer opinions embodying legal conclusions." *United States v. Scop, 846 F.2d 135, 139 (2d Cir. 1988)*; see also 4 *Weinstein's Federal Evidence § 704.04* ("In general, testimony about a legal conclusion, or the legal implications of evidence is inadmissible under *Rule 704*."). Indeed, the Court of Appeals for the Third Circuit has explicitly held that "it

is not permissible for a witness to testify as to the governing law," *United States v. Leo, 941 F.2d 181, 196 (3d Cir. 1991)*, [*5] or as to legal conclusions, see, e.g., *Berckeley Inv. Group Ltd. v. Colkitt, 455 F.3d 195, 218 (3d Cir. 2006)*.

Ten years ago, when this Court addressed the same issue, it noted that there was "some evidence that in patent cases courts relax the rule that expert witnesses cannot testify about the state of the law, or the application of the law to a specific factual situation." *Mars, Inc. v. Coin Acceptors, Inc., 1996 U.S. Dist. LEXIS 21514, at *3-4, No. 90-49 (D.N.J. July 2, 1996)*. [1] This is equally true today. Indeed, Teva directs the Court to several patent cases wherein a court permitted expert legal testimony. See, e.g., *Princeton Biochemicals, Inc. v. Beckman Coulter Inc., 2004 U.S. Dist. LEXIS 11918, at *69-70, 144-45, No. 96-5541 (D.N.J. June 17, 2004)*; *see also generally* Howard G. Pollack, The Admissibility and Utility of Expert Legal Testimony in Patent Litigation, 32 IDEA J. L. & Tech. 361 (1992). Pfizer, on the other hand, directs the Court to an equal number of patent cases wherein courts have refused to allow expert legal testimony. See, e.g., *Bausch & Lomb, Inc. v. Alcon Lab., Inc., 79 F. Supp. 2d 252, 258 (W.D.N.Y. 2000)*. [*6]

1 This Court explained that this relaxation of the rule,

> may be because patent law is a discipline pregnant with so-called "mixed questions of law and fact," such as anticipation [or] obviousness .... Testimony directed at these issues may understandably cross the neat boundary that typically separates fact testimony from legal conclusions. Perhaps another reason is that patent cases are, more often than other civil actions, tried without a jury, which means that the utility of the expert testimony is untarnished by the downside risk that the fact finder will confuse the roles of witness and judge.

*Mars, 1996 U.S. Dist LEXIS 21514, at *4* (internal citations omitted).

Having reviewed several of these conflicting cases, this Court remains of the opinion that [HN] "expert testimony that extends beyond factual presentation and approximates legal argument will not help the Court, but will indeed hinder it as non-evidential testimony prolongs what is already anticipated to be a lengthy bench [*7] trial." *Mars, 1996 U.S. Dist LEXIS 21514, at *7*; see also *W. R. Grace & Co. v. Viskase Corp., 1991 U.S. Dist. LEXIS 14651, at *2-3, No. 90 C 5383 (N.D. Ill. Oct. 15, 1991)* ("Both parties are represented by numerous patent lawyers. [Therefore, the] proffered [expert] testimony offers no meaningful assistance to the court as the trier of fact."). Accordingly, the Court will exercise its discretion and preclude Mr. Smith's testimony explicating the law generally or offering legal conclusions that follow from the facts presented at trial. He may not testify regarding his opinion that Pfizer's limited disclosure during prosecution of the patents-in-suit violates the best mode requirement, his opinion that Pfizer violated its duty of disclosure and the restriction requirement, or his opinion that the Merck *'995 patent* is material to patentability and not cumulative to the other references considered during the examination of the patents-in-suit.

Mr. Smith will be permitted to testify as to PTO practice and procedure (including the PTO's use of objective indicia of obviousness and the PTO's criteria for determining the weight and sufficiency of evidence [*8] purporting to demonstrate unexpected results in chemical cases), factual information regarding the prosecution history of the applications that issued as the patents-in-suit, and his opinion that Pfizer's expert's comparison of Celebrex to SC-58125 and to Vioxx do not demonstrate unexpected results. See *Mars, 1996 U.S. Dist LEXIS 21514, at *7*; *Revlon Consumer Prods. Corp. v. L'Oreal S.A., 1997 U.S. Dist. LEXIS 4117, at *2, No. 96-192 (D. Del. March 26, 1997)*. [2]

2 Pfizer argues that portions of the allowed testimony should be precluded under *Federal Rules of Evidence 402* and *403*. As an initial matter, the Court is not persuaded that the proposed testimony is irrelevant. Moreover, the Court cannot yet determine whether and to what extent this testimony will be cumulative, or a waste of time. The Court will entertain further objections on these grounds at trial.

/s/ John C. Lifland, U.S.D.J.

Dated: October 26, 2006

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EXHIBIT 7

LEXSEE 1997 US DIST LEXIS 4117

Positive
As of: Jul 13, 2007

REVLON CONSUMER PRODUCTS CORPORATION, Plaintiff, v. L'OREAL S.A., COSMAIR, INC., MAYBELLINE, INC., and MAYBELLINE SALES, INC., Defendants.

Civil Action No. 96-192 MMS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

1997 U.S. Dist. LEXIS 4117

March 26, 1997, Decided

NOTICE: [*1] FOR ELECTRONIC PUBLICATION ONLY

CASE SUMMARY:

PROCEDURAL POSTURE: After plaintiff consumer products company brought a patent infringement action against defendant competing companies, and after the competing companies counterclaimed, the consumer products company filed a motion to preclude the testimony of the patent law expert for the competing companies.

OVERVIEW: Alleging infringement of its patented composition for transfer resistant lipstick, a consumer products company brought an action against certain competing companies. The competing companies asserted a counterclaim seeking a declaratory judgment that the patent was invalid and that they had neither infringed nor induced infringement. The consumer products company filed a motion to preclude the testimony of a patent law expert for the competing companies. The parties agreed that the patent law expert could testify as to Patent and Trademark Office practice, but disagreed as to whether he could testify on the issue of inequitable conduct. The court ruled that he could not. The court opted to submit to the jury special interrogatories on the facts of materiality and intent, and then weigh the findings on those two elements in light of all the circumstances and decide the ultimate question of inequitable conduct. As a result, the court found that the jury would act as the sole fact-finder on the issue of inequitable conduct. The court concluded that, if it permitted expert testimony on inequitable conduct, it would usurp the respective functions of the jury and the court.

OUTCOME: The court ruled that it would admit testimony by the proffered patent law expert as to Patent and Trademark Office practice, but it would not admit testimony by the proffered patent law expert as to substantive issues of patent law, including inequitable conduct.

LexisNexis(R) Headnotes

Patent Law > Inequitable Conduct > Burdens of Proof
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Elements
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview

[HN1] Inequitable conduct has been defined by the Federal Circuit Court of Appeals as an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive. Information is material when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent. The proponent of a claim of inequitable conduct must prove the threshold elements of materiality and intent by clear and convincing evidence. The district court must then weigh the threshold findings of materiality and intent in light of all the circumstances to determine whether they warrant a conclusion that inequitable con-

duct occurred. A determination of inequitable conduct is committed to a district court's discretion.

Evidence > Testimony > Experts > Helpfulness
Evidence > Testimony > Experts > Qualifications
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
[HN2] *Fed. R. Evid. 702* states that if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise. Because the admission of expert testimony is a procedural matter not unique to patent issues, the law of the circuit court of appeals governs a motion to preclude expert testimony, as opposed to the law of the Federal Circuit.

Civil Procedure > Trials > Jury Trials > Province of Court & Jury
Evidence > Testimony > Experts > Admissibility
Evidence > Testimony > Experts > Helpfulness
[HN3] The decision whether to admit expert testimony is committed to the discretion of the district court. Several bases exist for excluding expert testimony. They are: (1) if the testimony will not assist the trier of fact, (2) if scientific or technical or other specialized evidence is not sufficiently reliable, and (3) if the particular expert does not have sufficient specialized knowledge to assist the jurors. The Third Circuit Court of Appeals adopts a broad interpretation of *Fed. R. Evid. 702*. Close calls on the admission of expert testimony are to be resolved in favor of admissibility. However, it is not permissible for a witness to testify as to the governing law since it is the district court's duty to explain the law to the jury.

Civil Procedure > Trials > Jury Trials > Jury Instructions > General Overview
Criminal Law & Procedure > Jury Instructions > Particular Instructions > General Overview
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN4] There are a variety of ways in which the district court may choose to handle the issue of inequitable conduct during a jury trial. Some courts reserve the entire issue of inequitable conduct unto themselves; some submit special interrogatories to the jury on the facts of materiality and intent; and some instruct the jury to find and weigh the facts of materiality and intent and decide the ultimate question of inequitable conduct. Absent a clear showing of prejudice, or failure to achieve a fair trial, the district court's choice of procedure will not be disturbed.

COUNSEL: Jack Blumenfeld, Esq., and Jon E. Abramczyk, Esq., of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware; Of Counsel: Daniel J. Leffell, Esq., Elizabeth J. Holland, Esq., and Douglas A. Berman, Esq., of Paul, Weiss, Rifkind, Wharton & Garrison, New York, New York; and John W. Behringer, Esq., of Fitzpatrick, Cella, Harper & Scinto; attorneys for plaintiff.

Rudolph E. Hutz, Esq., and Stanley C. Macel, III, Esq., of Connolly, Bove, Lodge & Hutz, Wilmington, Delaware; Of Counsel: Norman H. Stepno, Esq., Frederick G. Michaud, Jr., David M. Schlitz, Esq., and Ronni S. Jillions, Esq., of Burns, Doane, Swecker & Mathis, L.L.P., Alexandria, Virginia; and Norman F. Oblon, Esq., Richard D. Kelly, Esq., Jean-Paul Lavalleye, Esq., and Frank J. West, Esq., of Oblon, Spivak, McClelland, Maier & Neustadt, P.C., Arlington, Virginia; attorneys for defendants.

JUDGES: Murray M. Schwartz, Senior District Judge

OPINION BY: Murray M. Schwartz

OPINION

MEMORANDUM OPINION

Submitted on Briefs

Dated: March 26, 1997

Wilmington, Delaware

Schwartz, Senior District Judge

INTRODUCTION

Revlon Consumer Products Corp. ("Revlon") filed this lawsuit against [*2] L'Oreal S.A., Cosmair Inc., Cosmair Canada, Inc., [1] Maybelline, Inc. and Maybelline Sales, Inc. (collectively "defendants") alleging infringement of Revlon's patented composition for transfer resistant lipstick. *See* Docket Item ("D.I.") 61 (Amended Complaint). Three defendants, Cosmair Inc., Maybelline Inc., and Maybelline Sales Inc., asserted a counterclaim seeking a declaratory judgment that Revlon's patent is invalid and they have not infringed nor induced infringement.

1 Cosmair Canada, Inc. has since been dismissed as a defendant. D.I. 24.

Before the Court is Revlon's motion to preclude the testimony of defendants' patent law expert, John Witherspoon. D.I. 147. According to his report, Mr. Witherspoon proposes to offer opinions on a wide range of issues, including Patent and Trademark Office ("PTO") practice and procedure as well as many substantive areas

of patent law. [2] *Id.*, Exh. A at 2. The parties agree Mr. Witherspoon may testify as to PTO practice and procedure. D.I. 154, at 1; D.I. 157 [*3] at 2. Revlon asserts, however, the remainder of Mr. Witherspoon's proposed testimony goes to topics inappropriate for expert testimony in a patent case. D.I. 157, at 2. In their answer to Revlon's motion, defendants indicate other than PTO practice and procedure, they wish only to introduce Mr. Witherspoon's testimony on the issue of inequitable conduct. D.I. 154, at 1. Thus, to resolve Revlon's motion, the Court must decide whether to admit testimony by a proffered patent law expert on the topic of inequitable conduct.

> 2 Specifically, these areas are: "patent infringement, both literal and under the doctrine of equivalents; principles of claim construction and interpretation; prosecution history estoppel; conditions for patentability, including novelty, utility and nonobviousness under *35 U.S.C. §§ 101, 102* and *103*; requirements for and purposes of patent specifications and claims under *35 U.S.C. § 112*; the prohibition regarding the addition of new matter under *35 U.S.C. § 132*; duties and responsibilities of an inventor, his or her attorney or agent, and others substantively involved in the preparation and prosecution of a patent application in the PTO; and the prosecution history of the patent in suit." D.I. 147, Exh. A, at 2.

[*4] **DISCUSSION**

I. Inequitable Conduct

[HN1] Inequitable conduct has been defined by the Federal Circuit Court of Appeals as "an 'affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.'" *Micro Chemical, Inc. v. Great Plains Chemical Co., Inc., 103 F.3d 1538, 1549 (Fed Cir. 1997)* (citation omitted); *accord Refac International, Ltd. v. Lotus Development Corp., 81 F.3d 1576 (Fed Cir. 1996)*. "Information is 'material' when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." *Refac International,81 F.3d at 1581*.

The proponent of a claim of inequitable conduct must prove "the threshold elements of materiality and intent by clear and convincing evidence." *Micro Chemical, Inc., 103 F.3d at 1549*. "The district court must then weigh the threshold findings of materiality and intent in light of all the circumstances to determine whether they warrant a conclusion that inequitable conduct occurred." *Id.* "A determination of inequitable [*5] conduct is committed to a district court's discretion." *Id.*

II. Expert Testimony

Defendants assert Mr. Witherspoon's testimony as to inequitable conduct may assist the trier of fact and thus is admissible under *Federal Rule of Evidence 702*. [HN2] That rule states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

Because the admission of expert testimony is a "procedural matter" not unique to patent issues, the law of the Third Circuit Court of Appeals governs this motion, as opposed to the law of the Federal Circuit. *Panduit Corp. v. All States Plastic Manufacturing Co., 744 F.2d 1564, 1574-75 (Fed. Cir. 1984)*; *accord National Presto Industries, Inc. v. The West Bend Co., 76 F.3d 1185, 1188 n.2 (Fed. Cir. 1996)*.

[HN3] The decision whether to admit expert testimony is committed to the discretion of the district court. *United States v. Velasquez, 33 V.I. 265, 64 F.3d 844, 847-48 (3d Cir.* [*6] *1995)*. As might be gleaned from the rule, several bases exist for excluding expert testimony. They are: "(1) if the testimony will not assist the trier of fact; (2) if scientific [or technical or other specialized] evidence is not sufficiently reliable; and (3) if the particular expert does not have sufficient specialized knowledge to assist the jurors." *Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co., 998 F.2d 1224, 1238 (3d Cir. 1993)*; *see also Holbrook v. Lykes Bros. Steamship Co., Inc., 80 F.3d 777, 781 (3d Cir. 1996)*.

The Third Circuit Court of Appeals has adopted a broad interpretation of *Rule 702*; close calls on the admission of expert testimony are to be resolved in favor of admissibility. *Dunn v. Hovic, 28 V.I. 526, 1 F.3d 1362, 1367 (3d Cir. 1993)*. However, "it is not permissible for a witness to testify as to the governing law since it is the district court's duty to explain the law to the jury ...." *United States v. Leo, 941 F.2d 181, 196 (3d Cir. 1991)*. As relevant to Revlon's motion, Mr. Witherspoon's testimony will be inadmissible either if it is not helpful to the trier of fact, or if it constitutes impermissible testimony before the jury [*7] as to the governing law.

Defendants have not provided the details of Mr. Witherspoon's proposed testimony on inequitable conduct, beyond the sentence: "Defendants request that Mr. Witherspoon be allowed to testify as to the inequitable conduct issue if the Court determines that Mr. Witherspoon's testimony as a legal expert would assist in its determination." D.I. 154, at 2. Defendants' answer to Revlon's motion places into issue the currently unsettled question of whether, in this case, the judge or the jury will act as fact-finder on the issue of inequitable conduct.

With respect to that question, the Federal Circuit recently explained:

> [HN4] There are a variety of ways in which the district court may choose to handle the issue of inequitable conduct during a jury trial .... Some courts have reserved the entire issue of inequitable conduct unto themselves; some have submitted special interrogatories to the jury on the facts of materiality and intent; and some have instructed the jury to find and weigh the facts of materiality and intent and decide the ultimate question of inequitable conduct .... Absent a clear showing of prejudice, or failure to achieve a fair trial, the district [*8] court's choice of procedure will not be disturbed.

Hebert v. Lisle Corp., 99 F.3d 1109, 1114 (Fed. Cir. 1996). The court noted in the last instance the parties agreed to submit the entire issue of inequitable conduct to the jury. *Id.*

Failing to achieve similar agreement of the parties in the present case, the Court will opt to submit to the jury special interrogatories on the facts of materiality and intent. The Court will then weigh the findings on these two elements "in light of all the circumstances," and decide the ultimate question of inequitable conduct. *See Micro Chemical, Inc., 103 F.3d at 1549*; *see also Akzo N.V. v. U.S. International Trade Commission, 808 F.2d 1471, 1481-82 (Fed. Cir. 1986)* ("Materiality and intent must ... be considered together: the more material the omission or misrepresentation, the less intent that must be shown to reach a conclusion of inequitable conduct.")

As the determination of the Court consists of a 'weighing' of the factual findings on materiality and intent, and then a determination in light of all the circumstances whether inequitable conduct occurred, *see Micro Chemical, Inc., 103 F.3d at 1549*, it follows that [*9] the jury will act as the sole fact-finder on the issue of inequitable conduct. The Court therefore cannot permit Mr. Witherspoon to testify as an expert on inequitable conduct; to do otherwise would usurp the respective functions of the jury and the Court. [3]

> 3 The Federal Circuit recently noted one of the hazards of permitting expert testimony on patent law:
>
> > We take note of the extent to which . . . incorrect law was announced by a patent law expert witness. We encourage exercise of the trial court's gatekeeper authority when parties proffer, through purported experts . . . markedly incorrect law.
>
> *Hebert, 99 F.3d at 1117*.

In accordance with the other cases in this District, the Court holds defendants' expert John Witherspoon may testify only as to matters of PTO practice and procedure. *See Lucas Aerospace, Ltd. v. Unison Industries, L.P.*, No. 93-525 (D. Del. March, 9, 1995); *General Battery Corp. v. Gould, Inc., 545 F. Supp. 731, 758 n.30 (D. Del. 1982)*; *see also Thorn EMI North* [*10] *America Inc. v. Micron Technology, Inc.* No. 92-673 (D. Del. Nov. 23, 1993) (McKelvie, J.) (hearing transcript); *The Read Corporation v. Portec, Inc.*, No. 88-29 (D. Del. March 9, 1990) (Roth, J.) (hearing transcript); *RCA Corp. v. Data General Corp.*, No. 84-270 (D. Del. Dec. 17, 1986) (Farnan, J.) (hearing transcript); Guidelines: Legal Expert Testimony in Patent Cases (Robinson, J.). [4] Mr. Witherspoon may not testify as to substantive issues of patent law, including inequitable conduct. For purposes of clarity, it is noted this holding precludes, among other things, Mr. Witherspoon's proposed testimony regarding the "duties and responsibilities of an inventor, his or her attorney or agent, and others substantively involved in the preparation and prosecution of a patent application in the PTO ...." D.I. 147, Exh. A, at 2.

> 4 While this rule regarding patent experts is followed in this District, it is not uniform throughout the country. Several Federal Circuit cases refer, in passing, to expert testimony that was permitted on the topic of inequitable conduct, *see Hebert, 99 F.3d at 1115*; *Kingsdown Medical Consultants Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed. Cir. 1988)*.

[*11] An order will issue consistent with this opinion.

EXHIBIT 8

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446 AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

Jamiolkowski's statements. Ex. 8 at 163:11-20. Therefore, I believe Dr. Brookstein's assumption regarding the invention is inaccurate.

E. The coating added to Arthrex's FiberWire suture materially affects the pliability, handleability and physical properties of FiberWire

1. Coating materially affects suture handleability

It is my opinion that a person of ordinary skill in the art in February 1992 would understand the '446 patent to be teaching that coating materially affects suture handleability, including knot tiedown. For example, the '446 patent specification itself recognizes coating's effect on these properties where it states that coating the heterogeneous braid will "further improve the handleability and knot tiedown performance of the braid." Ex. 3 at col. 6, ll. 5-8.

Further, it was widely known and undisputed in the suture art in February 1992 that coating materially affects suture handling properties, including knot tie-down, and pliability. For example, there are many patents, including many Ethicon patents, that describe how coating affects these specific handling properties of suture. See, e.g., Ex. 9 at Abstract, col. 1, ll. 14-18; Ex. 10 at col. 1, ll. 11-15; Ex. 11 at col. 1, ll. 8-12; Ex. 12 at col. 1, ll. 12-15. There are also many articles on the subject as well. See, e.g., Ex. 13 at 525. I have also reviewed Ethicon documents stating the same thing. For example, in connection with the development of Ethicon's Panacryl suture, Ethicon stated that "the purpose of coating the Panacryl braided suture is to provide the suture with good

Dated: March 24, 2006

Debi Prasad Mukherjee, Sc.D.